

Anexa 16 Sigilator medical automat pentru pungi sterile, MelaSeal 300, Melag, Germania
(nu este dispozitiv medical conform declarației de conformitate)

Specificarea tehnică deplină solicitată, Standarde de referință	Specificarea tehnică deplină oferita, Standarde de referință
<p>Sigilator medical automat pentru pungi sterile Descriere: Mașină de sigilare medicală, sigilare automată a pungilor sterile Putere: $\geq 150W$ Display LCD "Mod de sigilare, tragerea automată a pachetului dupa detectarea pozitionarii" da, automat Încărcare: laterală Timp de incalzire: ≤ 10 sec. Temperatura de sigilare: minim 120 - 200°C Viteza de etanșare "nu mai puțin de 10 metri/min." Lățimea maximă de etanșare: min. 10 mm Distanța de etanșare față de margine "Min. 0 - 35 mm, reglabilă" "Oprire automată a motorului în cazul neutilizării dispozitivului" da Protecție la supraîncălzire: da Tensiune: 220V, 50Hz</p>	<p>Sigilator medical automat pentru pungi sterile Descriere: Mașină de sigilare medicală, sigilare automată a pungilor sterile Putere: max 650W Display LCD "Mod de sigilare, tragerea automată a pachetului dupa detectarea pozitionarii" da, automat Încărcare: laterală Timp de incalzire: de la 25 °C la 180 °C 100 sec. Temperatura de sigilare: minim 100 - 215°C Viteza de etanșare de la min 5 până la maxim 15 metri/min. Lățimea maximă de etanșare: 12 mm Distanța de etanșare față de margine "Min. 0 - 40 mm, reglabilă" "Oprire automată a motorului în cazul neutilizării dispozitivului" da Protecție la supraîncălzire: da, daca temperature > 220 °C Tensiune: 220V, 50Hz Parametri tehnici pot fi verificati in user manual, pagina 19 (distanța de etansare față de margine) și pagina 60 (restul parametrilor tehnici)</p>

EU-Konformitätserklärung

EU declaration of conformity

Hersteller / <i>Manufacturer:</i>	MELAG Medizintechnik GmbH & Co. KG
Adresse / <i>Address:</i>	Geneststraße 6-10, 10829 Berlin, Deutschland / <i>Germany</i>
Produkt / <i>Product:</i>	Durchlaufsiegelgerät / <i>Rotary Sealer</i>
Produktname / <i>Product name:</i>	MELAseal® 300
Angewandte Hauptnormen / <i>Applied main standards:</i>	EN ISO 13485 EN ISO 11607-2 EN 61010-1/-2-010 EN 61326-1 EN IEC 63000

Hiermit erklären wir in alleiniger Verantwortung, dass das oben aufgeführte Produkt den Anforderungen der nachfolgenden Richtlinien sowie deren Umsetzungen in nationale Gesetze entspricht.

Herewith, we declare under our sole responsibility that the product mentioned above meets the requirements of the following directives as well as their relevant transpositions in national laws.

2006/42/EG (Maschinenrichtlinie) / 2006/42/EC (Machinery directive)

Konformitätsbewertungsverfahren / <i>Conformity assessment procedure:</i>	Richtlinie 2006/42/EG Anhang VIII <i>Directive 2006/42/EC Annex VIII</i>
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2014/35/EU (Niederspannungsrichtlinie), 2014/30/EU (EMV-Richtlinie) und 2011/65/EU (RoHS-Richtlinie) 2014/35/EU (Low voltage directive), 2014/30/EU (EMC directive) and 2011/65/EU (RoHS directive)

Die Konformitätsbewertung wurde unter alleiniger Verantwortung des Herstellers durchgeführt.
The assessment of conformity has been done under the sole responsibility of the manufacturer.

Berlin, 30.07.2024



Sebastian Gebauer
(Geschäftsführer / *Managing director*)

User manual

MELAseal[®] 300

Sealing device

from software version 1.0.0



EN

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument reprocessing and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **“competence in hygiene”** and **“Quality – made in Germany”**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

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1 General guidelines




Please read this user manual carefully before commissioning the device. The manual includes important safety instructions. Make sure that you always have access to digital or printed version of the user manual.

Should the manual no longer be legible, is damaged or has been lost, you can download a new copy from MELAG download centre at www.melag.com.

Symbols used

Symbol	Description
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
	Draws your attention to important information.

Formatting rules

Example	Description
see Chapter 2	Reference to another text section within this document.
Sealing procedure	Words or phrases appearing on the display of the device are marked as display text.
	Prerequisites for the following handling instruction.
	Refer to the glossary or another text section.
	Information for safe handling.

Disposal

MELAG devices are synonymous with high quality and a long life-span. When you eventually need to decommission your MELAG device, the required disposal of the device can take place with MELAG in Berlin. Simply contact your stockist.

Dispose of accessories and consumption media which you no longer require in the appropriate manner. Comply with all relevant disposal specification in terms of possibly contaminated waste.

The packaging protects the device against transport damage. The packaging materials have been selected for their environmentally-friendly disposability and can be recycled. Returning the packaging to the material flow reduces the amount of waste and saves raw materials.

2 Safety



When operating the device, comply with the following safety instructions as well as those contained in subsequent chapters. Use the device only for the purpose specified in these instructions. Failure to comply with the safety instructions can result in injury and/or damage to the device.

Qualified personnel

- Only competent and trained personnel may use the device.
- The operator must ensure that the users are regularly trained in the operation and safe handling of the device.

Opening the housing

- Never open the device housing. Incorrect opening and repair can compromise electrical safety and pose a danger to the user. The device may only be opened by an [authorised technician](#) who must be a [qualified electrician](#).

3 Description of the device

Intended use

This sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices. It was especially developed for the heat sealing of instruments in sterilization packages and complies with the standards ▶EN ISO 11607-2 and ▶DIN 58953-7.

The Rotary sealing device MELAseal 300 is not a medical device as defined by the Medical Device Regulation.

Suitable materials

For the heat sealing of transparent sterilization packages in accordance with ▶EN 868-5 e.g. MELAfol reels and pouches are suitable. Should you wish to use any other packaging materials, please consult your stockist or contact MELAG directly.

Unsuitable materials

Sterilization packages that are not compatible with the requirements of EN 868-5, are incompatible with this device. The following materials are not suitable:

- Pure hose film (double-sided film), as these tends to become adhere to the sealing rail, and can restrict the functionality of the sealing device.
- Polythene film
- Soft PVC film
- Hard PVC film
- Polyamide film
- Polypropylene film

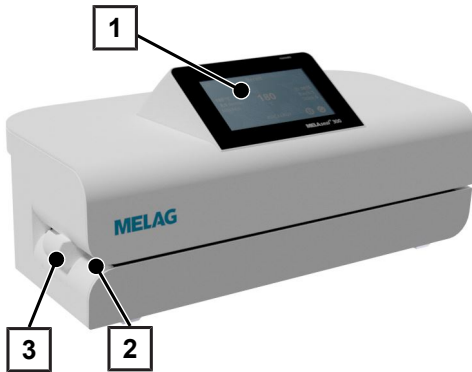
Scope of delivery

Please check the scope of delivery before setting up and connecting the device.

- Rotary sealing device MELAseal 300
- User manual
- Setup checklist and training protocol
- Declaration of conformity
- Warranty certificate
- Test and calibration protocol
- Power cable

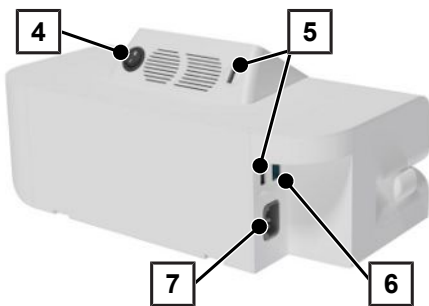
Views of the device

View from the front



- 1 Colour touch display
- 2 In-feed
- 3 Depth adjustment

View from rear



- 4 Power switch (On/Off)
- 5 USB connection
- 6 Ethernet interface
- 7 Power cable connection

Symbols on the device

Type plate



Manufacturer of the product



Date of manufacture of the product



Article number of the product



Serial number of the product



Observe user manual or electronic user manual



Do not dispose of product in household waste



CE marking



Electrical connection of the product: Alternating current (AC)

Symbols on the power switch



Switching on device



Switching off device

Touch display

The user interface consists of a colour 4.3-inch touch display. USB connections for data export (e.g. log output) and data import (e.g. software update) are located on the rear of the device.

PLEASE NOTE: The USB connection on the back of the display is exclusively for USB flash drives. Do not connect any other output media to this connection.

The representation in the areas is dynamic and changes depending on the status of the device.












Header area

The header area provides information about the currently opened menu and the status of the device.

The buttons or status icons are shown or hidden depending on the menu or the status of the device.









Button	Name	Description
	MENU	Open main menu
	EXIT	Exit current menu level
	OPEN	Open log for reading
	CONTINUE	Navigate forward within the menu level
	RETURN	Navigate backwards within the menu level
	DOWN	Navigate downwards within the display
	UP	Navigate upwards within the display
	OUTPUT	Open output settings for output status
	EDIT	Edit within the Settings menu level
	DEVICE STATUS	Open device data (e.g. serial number, real-time conductivity meter)

Symbol	Description
	User role service technician
	User role practice employee
	Computer connected
	MELAtrace connected
	Printer connected
	USB flash drive connected
	Sealing successful
	Sealing not successful
	Malfunction log

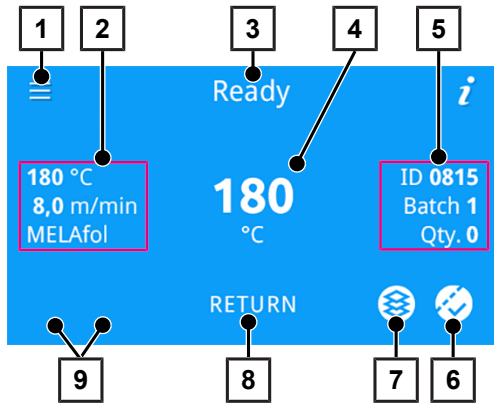
Main area

The device settings for activating/deactivating functions are made in the main area.

Messages and/or user instructions are displayed depending on the status of the device.

Button	Name	Description
	EDIT	Switch to the settings level
	SELECT	Change or select parameters
	SELECT	Change or select parameters
	ACTIVATE	Select several parameters, functions or output media <ul style="list-style-type: none"> • Blue background = selection/activation • Grey background = no selection/activation
	ACTIVATE	Selection of a parameter or a function <ul style="list-style-type: none"> • Blue tick = selection/activation • Grey tick = no selection/activation
	ENTER	Confirm entry
	KEYBOARD	Select country-specific keyboard
	OFF/ON	Activate (ON) or deactivate (OFF) functions <ul style="list-style-type: none"> • Blue background = active selection





Start screen structure



- 1 Open main menu
- 2 Display of TARGET temperature, TARGET speed, film type
- 3 Display of device status
- 4 Display of ACTUAL temperature/progress indicator
- 5 Display of user ID, batch number, number of seals in the batch
- 6 Open Seal Check
- 7 Start new batch
- 8 Start return
- 9 Switch between saved film types

LED display and acoustic signals

A safety system continuously monitors the sealing procedure. An acoustic signal is linked to the colour of the LED display and indicates an expected event.

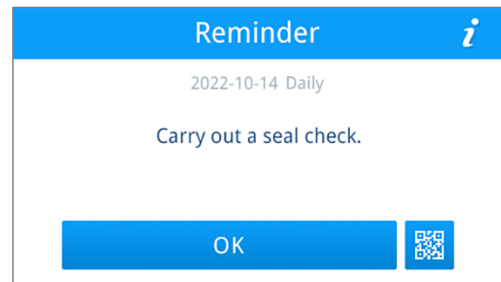
State LED		Description
	Blue	<ul style="list-style-type: none"> • Device started • Energy-saving mode • Software update is running • Device in operation • Sealing in progress
	Green	<ul style="list-style-type: none"> • Sealing successfully completed
	Yellow	<ul style="list-style-type: none"> • Warning message
	Red	<ul style="list-style-type: none"> • Malfunction • Sealing not successfully completed • Abort sealing

QR code

Further information on function tests, notifications, warnings and malfunction messages can be found on the MELAG website. A corresponding QR code will take you directly to the MELAG website.

1. Press .

Example view of the Seal Check reminder notification



➔ Important device data, such as the serial number, the MELAG web address and a QR code are displayed.

2. Scan the QR code.



➔ You are taken to the MELAG website.

4 Commissioning

Requirements of the installation location



CAUTION

Failure to comply with the setup conditions can result in injuries, malfunctions and/or damage to the device.

- Comply with all the specifications of this chapter for initial commissioning.
-

- The device is not suitable for operation in explosive atmospheres.
- The device is only intended for use in interior spaces.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.
- Install the device in a dry and dust-protected location.
- Maintain sufficient clearance to the surrounding surfaces in order to ensure sufficient ventilation.
- Ensure that the sealing device is located away from direct sunshine and outside the range of other sources of heat.
- Setup the device protected against blows or vibrations.

Removing from the packaging

1. Open the transport packaging carefully.
2. Remove the device from the transport packaging.
3. Check the device for any damage suffered during transport.

Connecting the sealing device

Comply with the following for safe handling:

- Comply with all legal requirements and locally-specified connection conditions.
 - Never operate the device if the plug or power cable are damaged.
 - Never damage or alter the power plug or cable.
 - Never bend and twist the power cable.
 - Never unplug by pulling on the power cable. Always take a grip on the plug.
 - Ensure that the power cable does not become jammed in.
 - Never place any heavy objects on the power cable.
 - Never lead the cable along a source of heat.
 - Never fix the power cable with sharp objects.
 - The mains socket must be freely accessible after installation so that the device can be disconnected from the electrical mains at any time if necessary by pulling the mains plug.
-



NOTICE

Warning of material damage due to operation outside the specified ambient temperature.

Operating the device outside the specified ambient temperature (5-40 °C) can lead to damage to individual device components (e.g. circuit boards, vacuum pump, etc.).

- Allow the device to acclimatise to the required ambient temperature (5-40 °C) before switching it on for the first time.
-

The following must be fulfilled or present:

- ✓ The sealing device has been switched off.
- ✓ The power cable, delivered in the scope of delivery, is present.

1. Connect the power cable to the back of the device.



2. Plug the power plug of the device into the power socket of the practice.

Switching on the device

The following must be fulfilled or present:

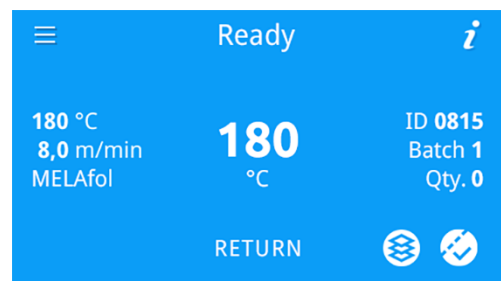
- ✓ The device is connected to the power supply.

1. Switch on the device at the power switch.



- ➔ When switching on for the first time or if the device has not yet been set (configured), the configuration wizard opens, see [Configuring the device](#) [▶ Page 16].
- ➔ If authentication is activated, the user prompt appears, see [Authenticate user](#) [▶ Page 17].
- ➔ Once the device has been configured, the start screen appears.

2. Wait until the device has reached the required sealing temperature.



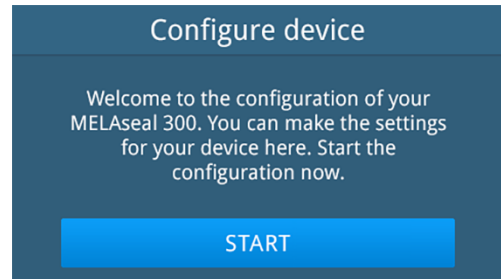
- ➔ **Ready** appears on the display.

Configuring the device

The configuration wizard appears automatically when the device is started for the first time and helps you with the setting. To ensure that the configuration wizard does not appear every time the device is started, it must be run through once completely. It is possible to interrupt the configuration wizard at any time and continue at a later time, see [Configuring the device](#) [▶ Page 51].

Configure the device as follows:

1. Press **START** to start the configuration wizard.

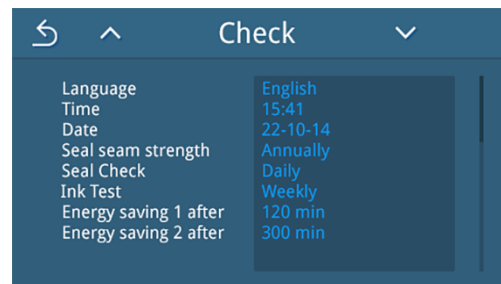


2. Follow the configuration wizard and configure the device according to your requirements.

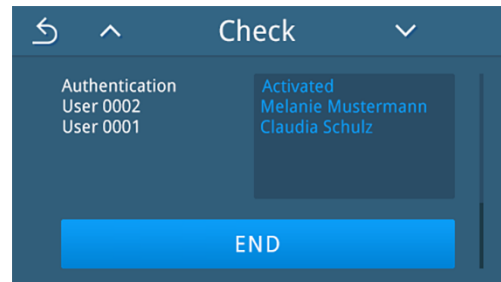
➔ For more detailed information on the individual setting options, see [General settings](#) [▶ Page 28].

3. Check your settings in the displayed overview.

Example view of device settings



4. Press **END** to end the configuration wizard and restart the device.




Authenticate user

You have the option of activating or deactivating the user authentication, see [Authentication](#) [▶ Page 44]. If authentication is activated, the user is prompted to authenticate themselves with their ID or user name and PIN when the device starts. The user ID is documented in the sealing log.

Log in user

- ✓ The device is switched on.
- ✓ At least one user has been created.

1. Select the relevant user ID or user name from the user list and press .



2. Enter the associated PIN.



- ➔ The start screen appears.
- ➔ The user ID appears on the executed logs.

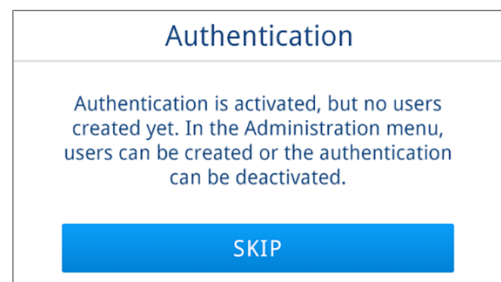
Skip login

Regardless of whether users have been created, you can skip the login.

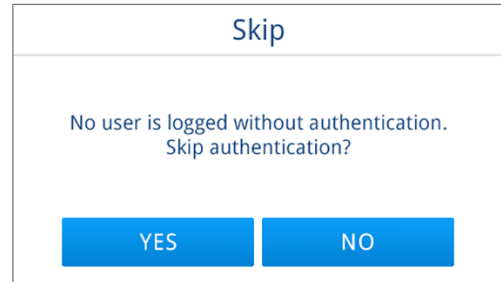
- ✓ The device is switched on.

1. Press **SKIP**.

Example view of login without created users.




2. Confirm the notification with **YES**.

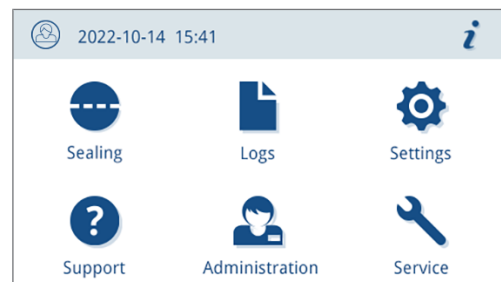


- ➔ The start screen appears.
- ➔ No user ID appears on the logs.

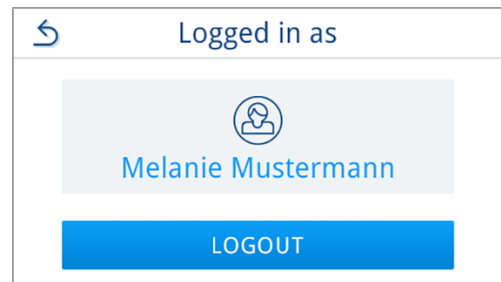
Log out user

- ✓ A user is logged in.

1. In the main menu, press .



2. Press **LOGOUT**.



- ➔ No more users are logged in.
- ➔ The user list appears.

Checking date and time

Date and time of the device must be correctly set for proper documentation. Ensure that you take into account any clock change, as this is not adjusted automatically. Proceed as follows if the device has not yet been set:

1. Switch to the main menu.
2. Check the date and time in the header of the display.
3. If necessary, set the date and time in the **Settings** menu, see [Date](#) [▶ Page 28] and [Time](#) [▶ Page 29].

Setting the display and audio

If necessary, adjust the brightness in the **Settings** menu and activate/deactivate the signal tone, see [Display](#) [▶ Page 30] and [Audio](#) [▶ Page 31].

5 Sealing

Setting the clearance between the seal seam and the cutting edge of the packaging

The sealing device permits individual setting of the clearance of the seal seam to the cutting edge of the packaging. The depth adjustment is located on the left-hand side of the sealing device. The scale beneath it displays the overhang in millimetres (measured from the outer edge of the sealed seam).

- ▶ Set the depth adjustment to the required position.



Sealing procedure

Comply with the following for safe handling:

- Ensure that small components (e.g. from instrument) do not enter the in-feed with the sterilization package to be sealed. The small components could cause damage to the transport mechanism of the device, the sterilization material and the sterilization package.
- Never introduce any objects into the sealing device other than the packaging materials specified in the user manual.
- When sealing MELAfol pouches with a side gusset, ensure compliance with the manufacturer's specifications (e.g. Instructions for handling MELAfol pouches with side gusset) especially when wishing to seal cassettes.

The following must be fulfilled or present:

- ✓ The sealing temperature has been reached.
- 1. Insert the transparent sterilization package in the in-feed on the left-hand side of the device.


PLEASE NOTE: MELAG recommends guiding the packaging through the device with the film side pointing upwards.

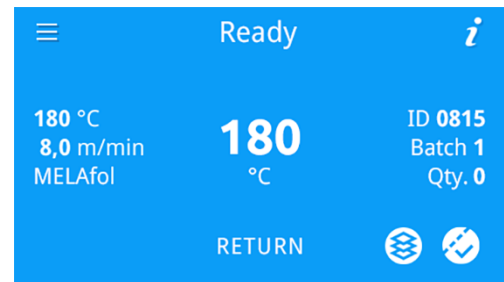
↳ As soon as the device detects the wrapping, the wrapping is carried out automatically.

- 2. Remove the transparent sterilization package on the right-hand side of the device.

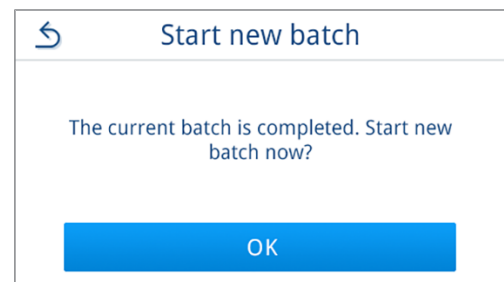
Batch counter

You can combine several seals in one ▶**batch**. This can be, for example, seals that are reprocessed together in one operating cycle. The display shows the number of seals.

1. Press  on the start screen to start a new batch.



2. Confirm with **OK**.



- The batch number is incremented.
- The number of seals is reset to zero.

6 Logging

Documenting the sealing procedure

▶ [EN ISO 11607-2](#) requires that the sealing process must be monitored and documented. As a result, you are able to record the logs of the sealing procedures, to output and archive them on the following output media:





- USB flash drive
- MELAprint 80 universal printer
- FTP server
- MELAtrace documentation software (from software version 4.2)

The device stores a limited number of logs internally. When the device memory is full, the oldest log is overwritten. You can output internally stored logs manually to a USB flash drive at any time.

The automatic logging of sealing procedures is deactivated by default. MELAG recommends activating the automatic logging function. For direct output, activate the log output for the respective output medium, see Log output.

Output media

You are able to output and archive the logs of the completed sealing procedures on the following output media:

Symbol	Output medium	Description
	FTP server	Output to an FTP server
	MELAprint 80	Output of logs to a connected printer
	USB flash drive (rear of the device)	Storage on a USB flash drive
	MELAtrace	Output to MELAtrace



PLEASE NOTE

You can only connect one USB storage medium.

The USB connection on the back of the display is exclusively for USB flash drives. The printer is connected via USB at the rear of the device.

Displaying logs on the computer

The log files are generated in HTML format and can be displayed and printed on the computer with a web browser or in MELAtrace.

PLEASE NOTE: The log files are provided with a proof of authenticity to identify tampering.

Example log

```

MELAG MEDIZINTECHNIK
-----
020 MELAG MELAseal 300
040 Date (YYYY-MM-DD):      2024-02-22
160 Serial Number:          20243001001
200 Software Version:       1.100
336 Service Date (YYYY-MM-DD): 2028-03-20
-----
|Stat|Time   |Speed|Temp|Force|Limits-Speed, Temp, Frc|User|SCnt|BatchCnt|BatchID|Service|Total|CS
|----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
OK|08:01:09|08.5|180|060|07.5-09.5 175-185 50-70|0815|00001|00001|00001|049991|0000009|XXX
OK|08:01:22|08.5|179|062|07.5-09.5 175-185 50-70|00002|00002|00001|049990|0000010|XXX
OK|08:01:30|08.5|181|063|07.5-09.5 175-185 50-70|----|00003|00001|00002|049989|0000011|XXX
-----next line Seal Check-----
OK|08:01:49|08.4|180|065|07.5-09.5 175-185 50-70|1111|00004|00001|00003|049988|0000012|XXX
-----Seal Check not OK-----
-----next line Seal Check-----
OK|08:02:49|08.4|180|065|07.5-09.5 175-185 50-70|1111|00005|00002|00003|049987|0000013|XXX
-----Seal Check OK-----
OK|08:04:05|08.5|180|062|07.5-09.5 175-185 50-70|1111|00006|00001|00004|049986|0000014|XXX
F6|08:04:13|08.4|180|[071]|07.5-09.5 175-185 50-70|1111|00007|00002|00004|049985|0000015|XXX
F12|08:07:15|00.0|180|050|07.5-09.5 175-185 50-70|1111|00007|00002|00004|049985|0000015|XXX
    
```

Using the USB flash drive as an output medium



NOTICE

Danger of data loss through damage of the USB flash drive following improper use.

- Do not exert any force on the USB flash drive whilst inserting it.

Should you wish to save the log of a sealing procedure on the USB flash drive automatically, connect it as follows:

1. Switch off the sealing device.
2. Insert the USB flash drive into one of the device's two USB ports.



3. Switch on the sealing device.

Logs menu

The **Logs** menu provides you with the following options:

- Display and output of sealing logs
- Display and output of malfunction logs
- Output of status logs

Log types

Log type	Description
Sealing logs	Log of a sealing procedure
Malfunction log	Log with malfunctions that occurred outside a program run
Status log	Summary of all important settings and system statuses

You can issue logs subsequently and independently of the time of the sealing. Before the log output, you can select the output media.

List of logs

All logs of the internal log memory are displayed in a log list depending on the log type. The list is sorted by date (and time), i.e. the newest log is always added at the top of the list. You can navigate up and down within the list.

- ▶ **Program log list:**
 - a) Date
 - b) Number of successful sealing procedures
 - c) Number of device malfunctions

Date	✓	⚠
2022-10-14	8	2
2022-10-14	135	5
2022-10-13	28	0
2022-10-10	201	0

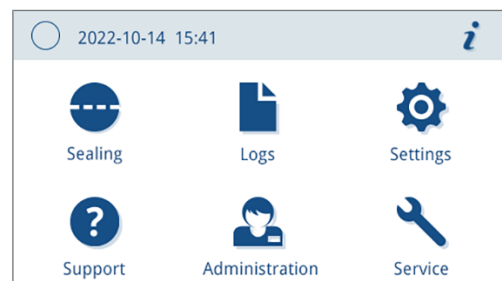
Subsequent log output

PLEASE NOTE: For subsequent log output, logs can only be output on a USB flash drive. Output via another medium is not possible.

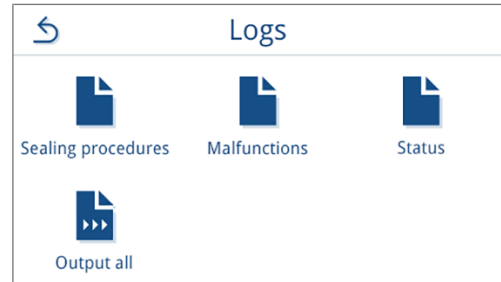
The following must be fulfilled or present:

- ✓ A USB flash drive is connected.
- ✓ Log output via USB flash drive is activated, see Log output.

1. In the main menu, press **Logs**.



- Select the log type to be output.



→ A list of the selected log type appears.

- Select a log from the list.

Example view of sealing log list.

Date	Sealing	Malfunctions
2022-10-14	8	2
2022-10-14	135	5
2022-10-13	28	0
2022-10-10	201	0

→ The log is displayed.

- Press to output the log.

Example view of a sealing log.

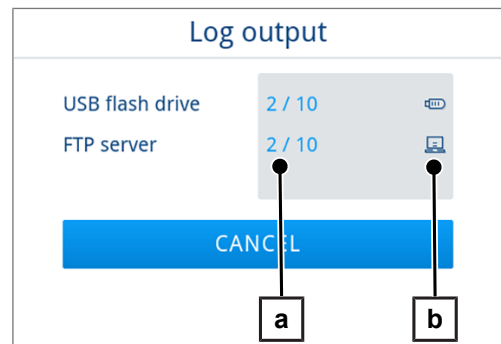
Time	Batch	Sealing	Status
08:01:09	2	4	✓
08:01:07	2	3	✓
08:01:02	2	2	⚠
07:56:13	2	1	✓

- Follow the progress of the log output on the display.

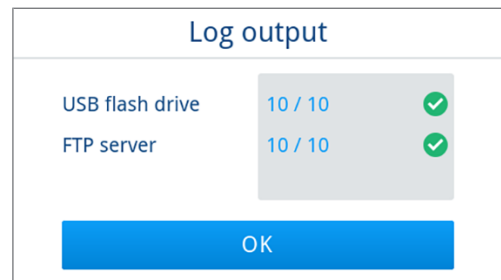
If the log output was not executed or not completed by pressing **ABORT**, an unsuccessful/incomplete output result is displayed.

NOTICE! Premature removal of the USB flash drive or inappropriate handling can result in data loss, damage to the USB flash drive, the device and/or the software.

- a) Number of logs output
- b) Symbol of output medium



- The result (successful/unsuccessful) is displayed after the log output. Press **OK** to confirm the result.



7 Function checks

Function check with MELAcontrol Seal Check

The MELAcontrol Seal Check serves to check the function of the seal seam produced by your sealing device. MELAG recommends performing this function check once a day during operation.

The device is fitted with a reminder function which reminds e.g. at the daily seal check.

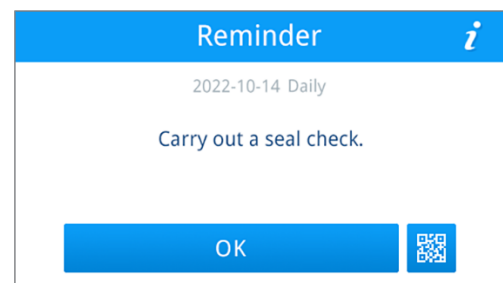
MELAG recommends setting the reminder function, see [Reminders](#) [▶ Page 46].

Performing a MELAcontrol Seal Check


The following must be fulfilled or present:

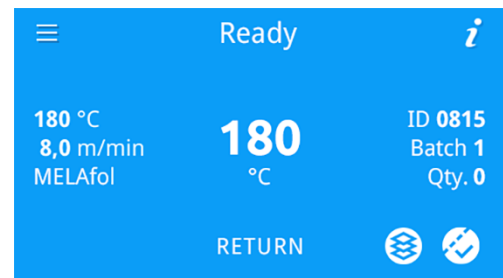
- ✓ MELAcontrol Seal Check (available separately)
- ✓ Transparent sterilization package (width min. 10 cm and length min. 18 cm)

1. With the reminder function set: Press **OK** to perform the Seal Check directly.



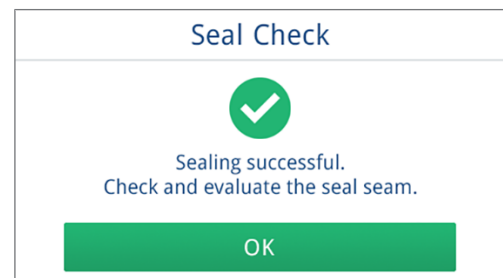
2. Prepare the MELAcontrol Seal Check test strip with the transparent sterilization package in accordance with the applicable instructions for use.

3. Press  to perform a test seal.



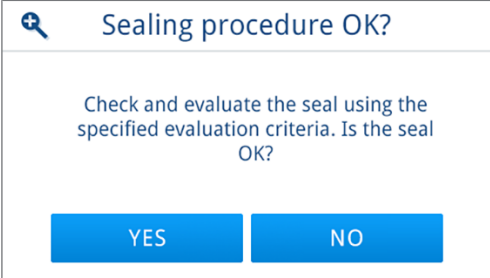
4. Seal the prepared transparent sterilization package.

5. Press **OK**.



6. Check the seal seam.

7. The option for seal seam evaluation is displayed:
Press **YES** if the seal seam meets the criteria.
Press **NO** if the seal seam does not meet the criteria and repeat the test seal.



Sealing procedure OK?

Check and evaluate the seal using the specified evaluation criteria. Is the seal OK?

YES NO

→ The result of the Seal Check is recorded.

Performing a MELAcontrol InkTest

The MELAcontrol Ink Test is a reliable test for routine control of the seal seam for leaks. The MELAcontrol Ink Test can also be used for bags with a side gusset.

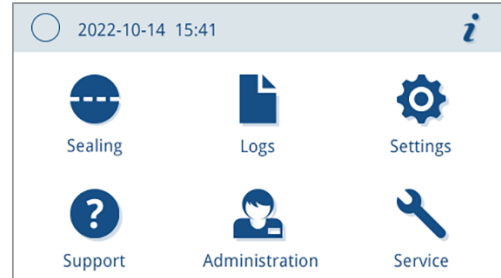
- ▶ Carry out weekly seal seam checks with a MELAcontrol Ink Test.

For further information, see the MELAcontrol Ink Test instructions for use.

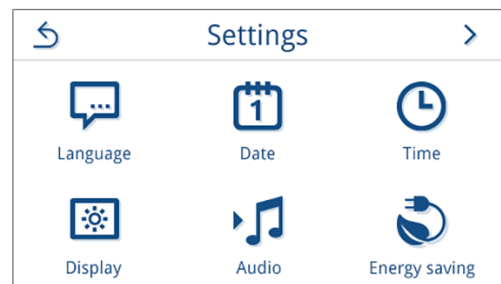
8 Settings

Parameters such as language, date, etc. can be set in the submenus of the **Settings** menu.

1. In the main menu, press **Settings**.



2. Make settings in the corresponding submenus.

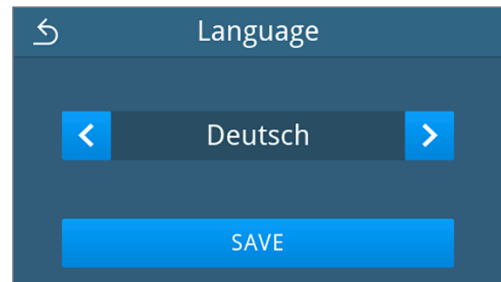


➔ After saving, settings are immediately applied and the view changes from the respective submenu back to the **Settings** menu.

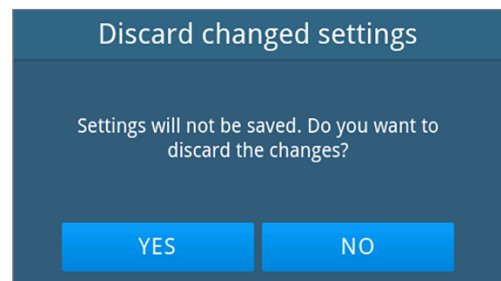
➔ It is not necessary to restart the device.

Discard changed settings

1. Press **↶** without saving in the header area of the respective submenu to cancel a selection or entry made.



2. Select **YES**.



➔ The view changes from the respective submenu back to the **Settings** menu.

➔ If settings are cancelled before saving, the previous parameters remain unchanged.

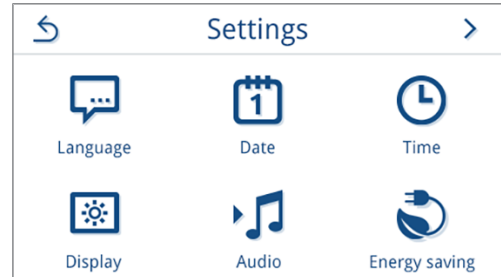
General settings

General settings can be changed by any user.

Language

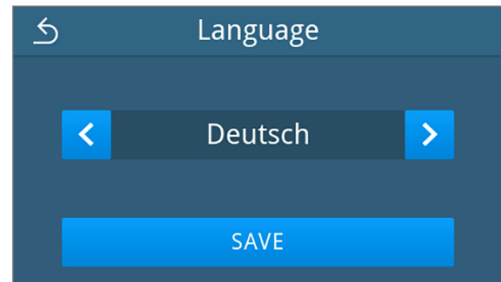
You can switch between the enabled languages in the Language submenu.

1. Press **Language** in the **Settings** menu.



2. Select the desired language using **<** or **>**.
 ↳ After a setting has been changed, the **SAVE** button is active.

3. Confirm with **SAVE**.

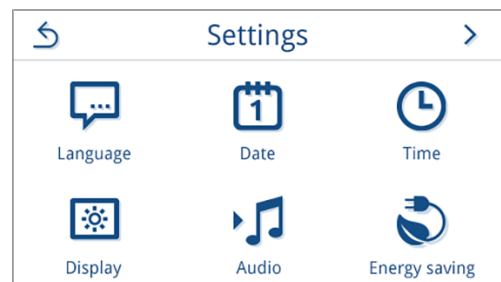


↳ The dialogues on the display and the log texts are changed to the selected language. The view switches back to the **Settings** menu.

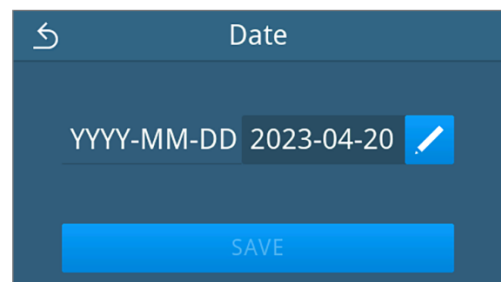
Date

The date of the device must be correctly set for proper batch documentation. Set the date as follows:



1. Press **Date** in the **Settings** menu.



2. Press **✎**.



↳ The calendar view opens.

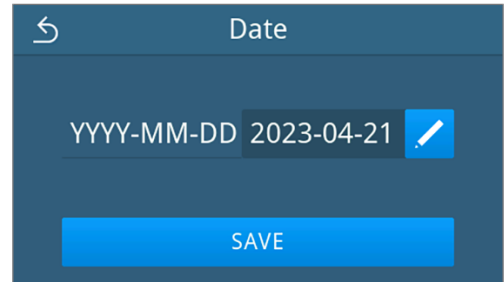
3. Select the correct date in the calendar.
Press  (past) or  (future) to select the month.

TIP: Long press = 1-year increments



➔ After a setting has been changed, the **SAVE** button is active.

4. Press **SAVE**.

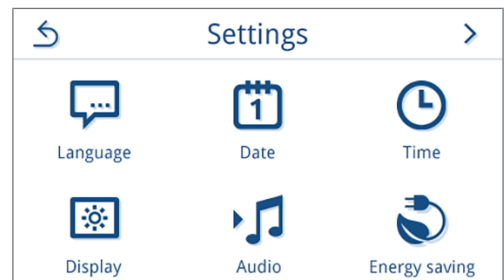


➔ The view switches back to the **Settings** menu.

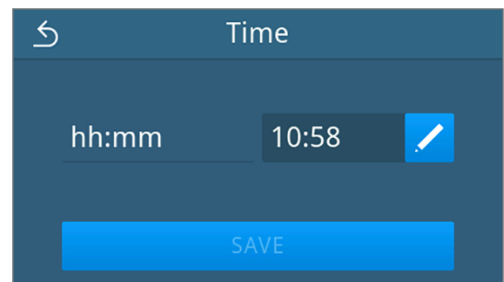
Time

The time of the device must be correctly set for proper batch documentation. Ensure that you take into account any clock change, as this is not adjusted automatically. Set the time as follows:

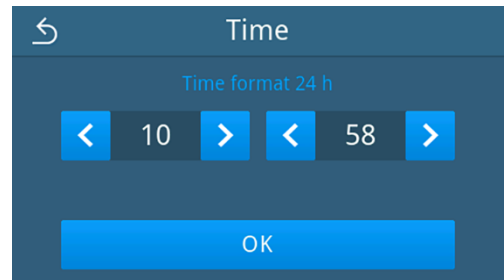
1. Press **Time** in the **Settings** menu.



2. Press .

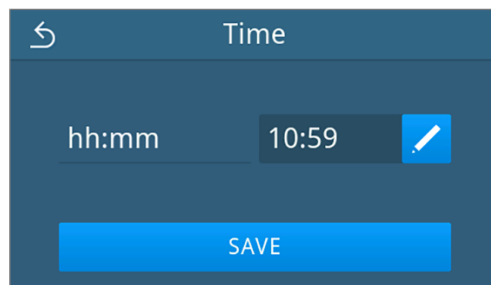


3. Set the correct time using  or  and confirm with **OK**.



➔ After a setting has been changed, the **SAVE** button is active.

4. Press **SAVE**.

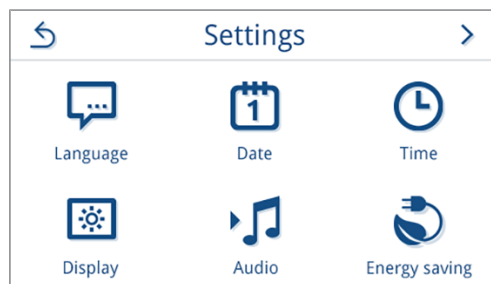


→ The view switches back to the **Settings** menu.

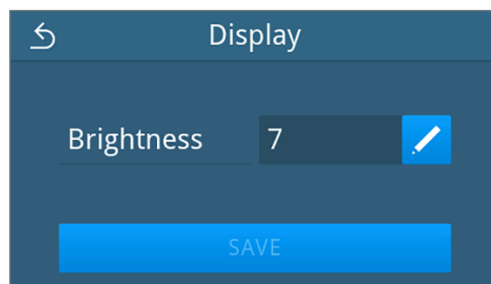
Display

Individualise the display brightness.



1. Press **Display** in the **Settings** menu.



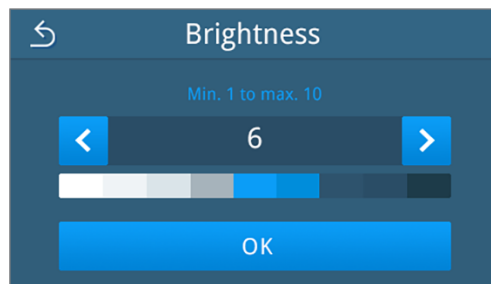
2. Press .



3. Press one of the buttons to change the brightness of the display. The display brightness can be adjusted in several steps.

-  Set the display darker
-  Set the display brighter

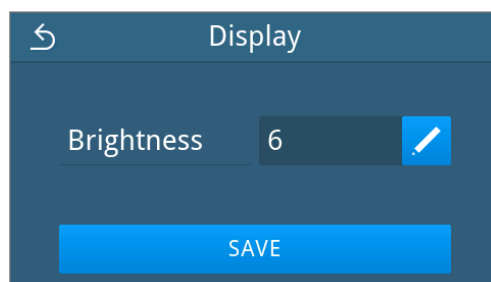
The colour bar below the value display gives you an impression of the colour contrast. The brightness is adjusted immediately.



4. Press **OK** to confirm the setting.

→ After a setting has been changed, the **SAVE** button is active.

5. Press **SAVE**.

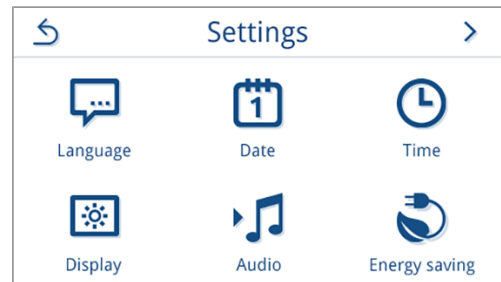


→ The view switches back to the **Settings** menu.

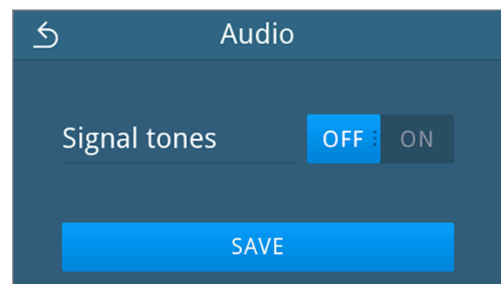
Audio

You can activate (ON) or deactivate (OFF) the signal tones in the **Audio** submenu. The signal tones are activated by default.

1. Press **Audio** in the **Settings** menu.



2. Select the desired setting by pressing **OFF/ON**.
 - ↳ After a setting has been changed, the **SAVE** button is active.
3. Press **SAVE**.



↳ The view switches back to the **Settings** menu.

Energy saving

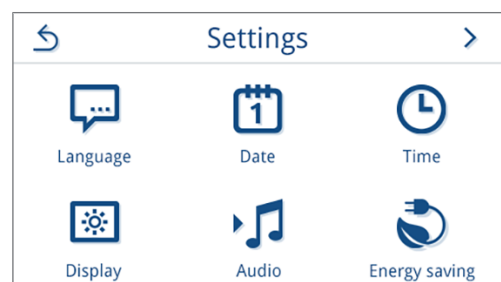
Energy-saving mode consists of two levels. In level 1 the heater is reduced and the display is switched off. In level 2 the heater is switched off. In the delivery state, level 1 is activated after 5 min and level 2 after 15 min.

The following functions are deactivated:

- The display is switched off during energy-saving mode and is only switched on with a touch.
- The heater is reduced or switched off and is only activated when the display is touched.

Setting the activation period of energy-saving mode

1. Press **Energy saving** in the **Settings** menu.



2. In **Level 1/Level 2**, press .

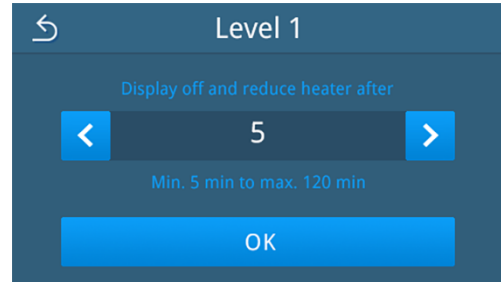


- Press **<** or **>** to shorten or lengthen the time until energy-saving mode is activated.

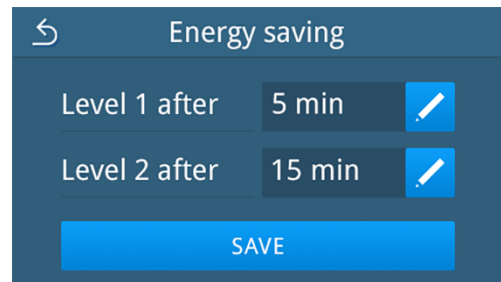
TIP:

short press = increments of 1
 long press = increments of 5

Example view of Level 1



- Press **OK** to confirm the setting.
 - After a setting has been changed, the **SAVE** button is active.
- Press **SAVE**.



→ The view switches back to the **Settings** menu.

Manually ending active energy-saving mode

- Press the switched off display if necessary.
 - The display is switched on.

PLEASE NOTE: Activating the display ends energy-saving mode.

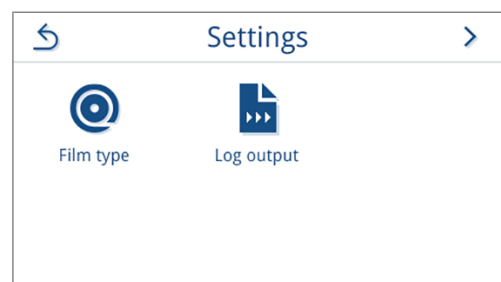
→ The previous view is displayed again.

Film type

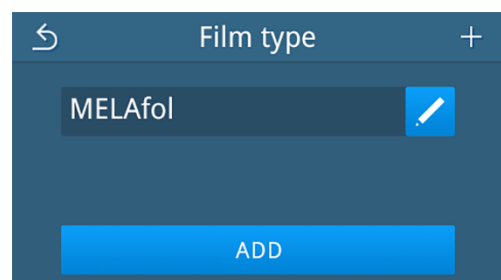
For faster operation, you can save the sealing temperature and conveyor speed for each film type you use in your practice. MELAfol is stored by default.

Creating a slide type

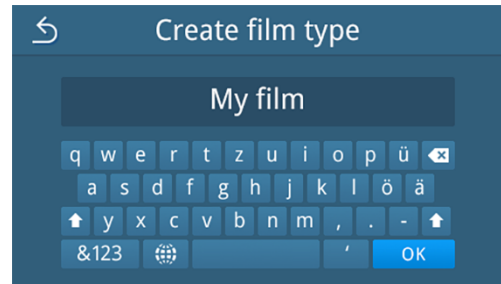
- Press **Film type** in the **Settings** menu.



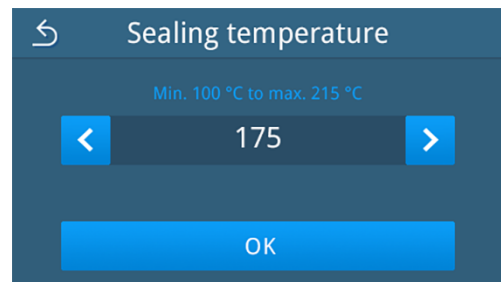
- Press **ADD** or **+** to create a new film type.



3. Enter a name for the new film type and press **OK** to confirm.

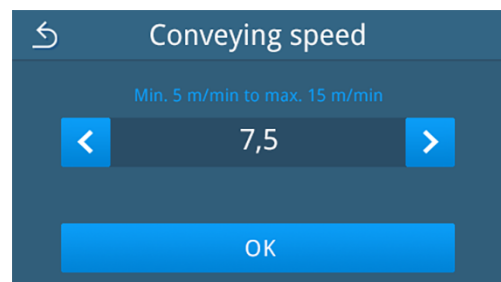


4. Select the desired sealing temperature by pressing **<** or **>**.



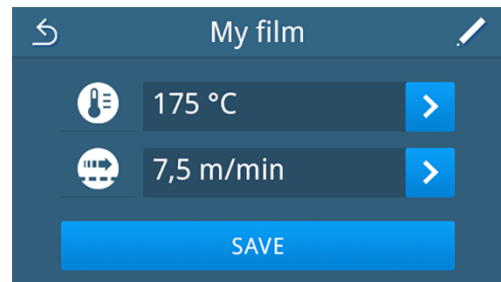
5. Press **OK** to confirm the setting.

6. Select the desired conveying speed by pressing **<** or **>**.



7. Press **OK** to confirm the setting.

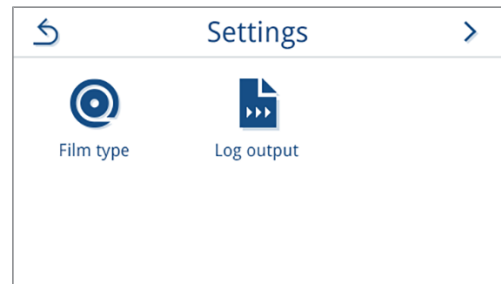
8. Press **SAVE**.






→ The new film type is displayed in the **Settings > Film type** menu.

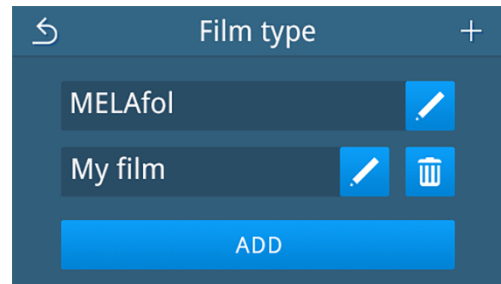
Editing a slide type




1. Press **Film type** in the **Settings** menu.

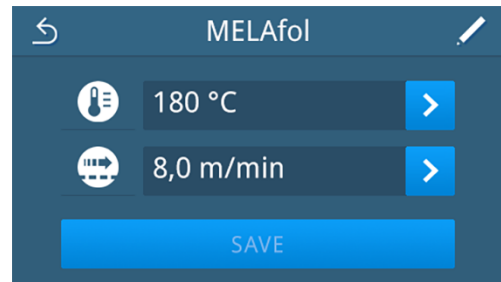


2. Press  to edit the selected film type.

Press  or  to scroll through the list.

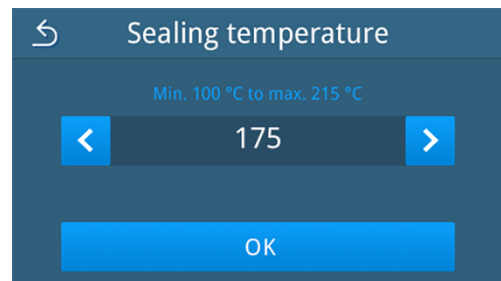


3. Press  to adjust the sealing temperature /conveying speed .



4. Select the desired film type/conveying speed by pressing  or .

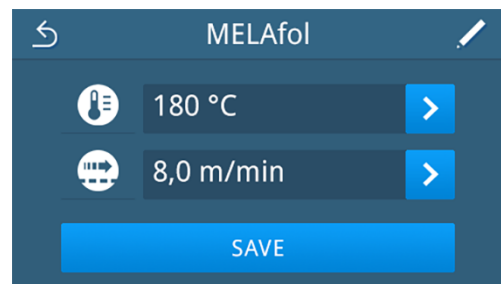
Example view of the sealing temperature



5. Press **OK** to confirm the setting.

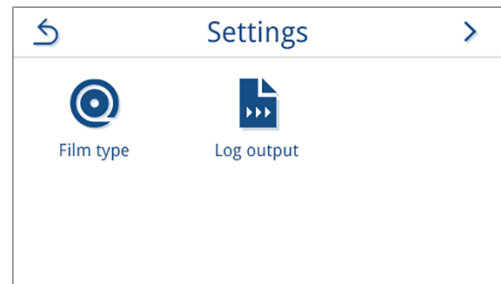
 After a setting has been changed, the **SAVE** button is active.


6. Press **SAVE**.





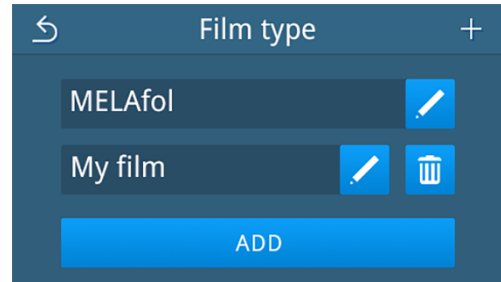
Deleting a slide type

1. Press **Film type** in the **Settings** menu.

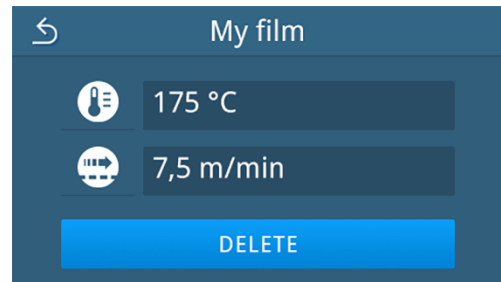


2. Press  to delete an entry. The MELAfol film type cannot be deleted.

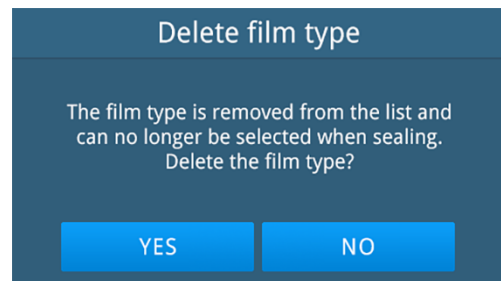
Press  or  to scroll through the list.



3. Press **DELETE**.



4. Confirm the query with **YES**.



Log output

In the **Log output** submenu, you can set how the log should be output by default for each output medium. Log output is deactivated by default.

ON: The log is output automatically at the end of the sealing procedure.

OFF: No log output is possible, even with output medium connected.

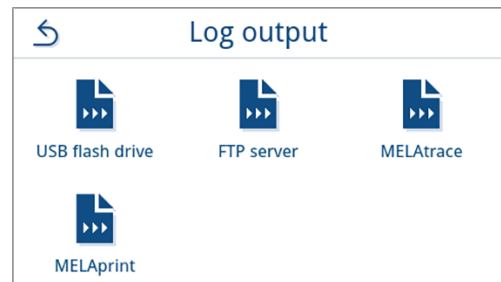
Log output on a USB flash drive

✓ An output media is connected.

1. Press **Log output** in the **Settings** menu.

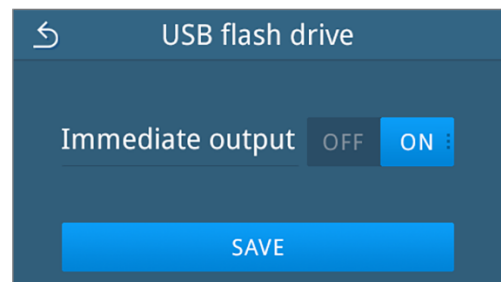


2. Press **USB flash drive**.



3. Press **ON** or **OFF** to activate or deactivate the immediate output.

4. Press **SAVE**.



➔ The selection has been set as default. The view switches back to the **Log output** submenu.

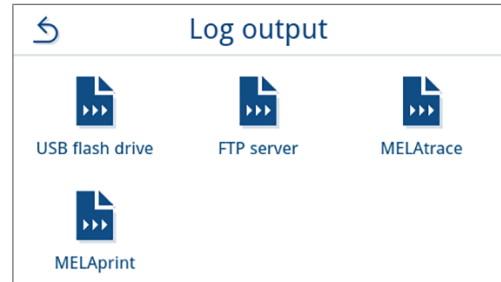
Log output with MELAprint

You can configure the log printer in the **MELAprint** submenu. Connect to a printer via USB or network (LAN). Also select between manual and automatic output or deactivate log printing. Log printing is deactivated by default.

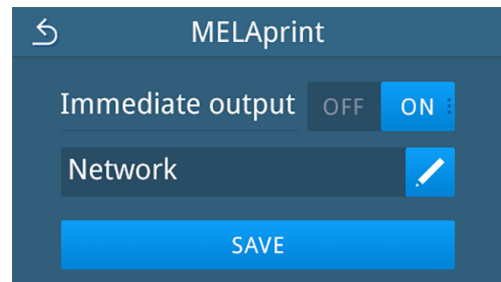
1. Press **Log output** in the **Settings** menu.



2. Press **MELAprint**.



3. Press **ON** or **OFF** to activate or deactivate the immediate output.




4. Press **SAVE**.

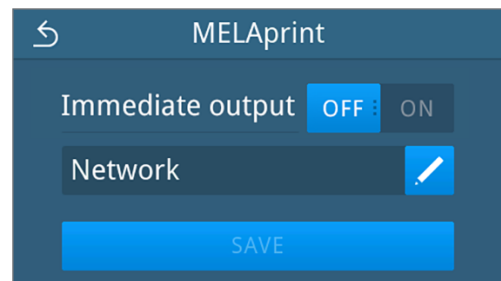
↳ The selection has been set as default. The view switches back to the **Log output** submenu.


5. Set up the printer, see [Configuring the log printer](#) [▶ Page 37].

Configuring the log printer

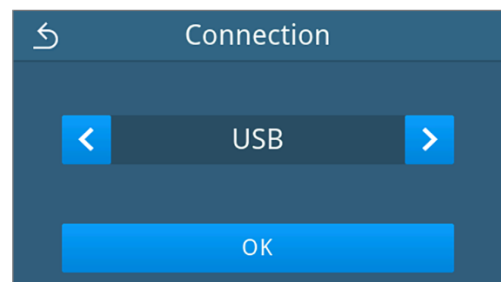
Printer via USB

1. Configure the printer by pressing  in the bottom row.



2. Select **USB** by pressing  or .

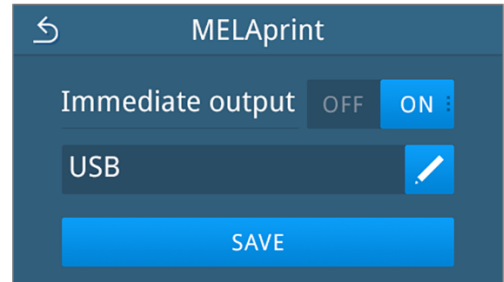
Then confirm with **OK** to accept the selection.



↳ The edited configuration is displayed.

3. Press **SAVE**.

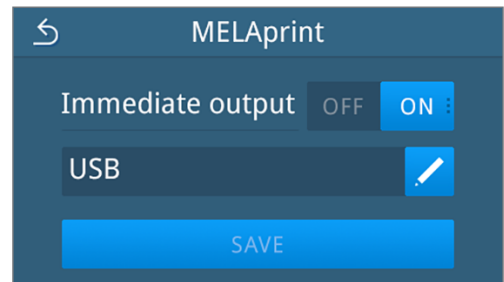
Example view of a selected configuration.



→ The selection has been set as default and the view changes back to the **Log output** submenu.

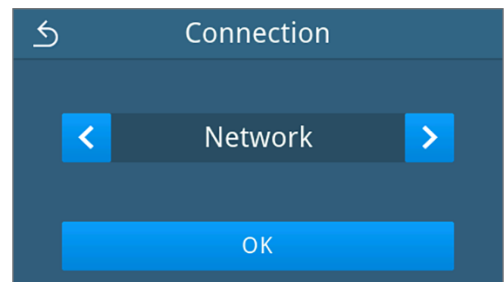
Printer via network

1. Configure the printer by pressing in the bottom row.



2. Select **Network** by pressing or .

Confirm with **OK** to start searching for a network printer.

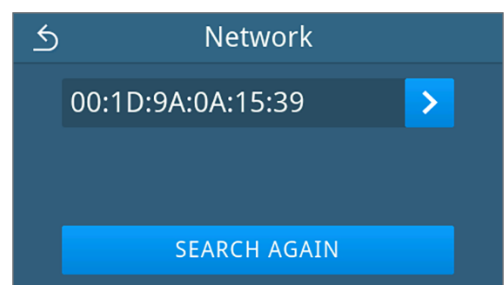


3. If no printer was found, you can start the search again by pressing **SEARCH AGAIN**.

4. If printers are found in the network, they are displayed in a list with their MAC address for selection.

PLEASE NOTE: If several printers are found in the network, you can scroll through the MAC addresses by pressing or .

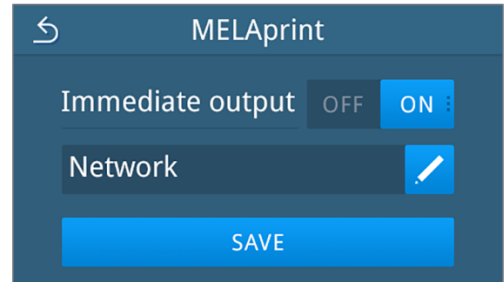
Press to select the desired printer.



→ The edited configuration is displayed.

5. Press **SAVE**.

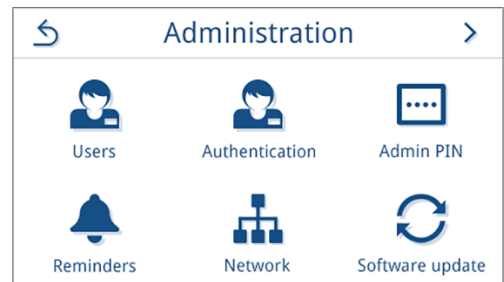
Example view of a selected configuration.



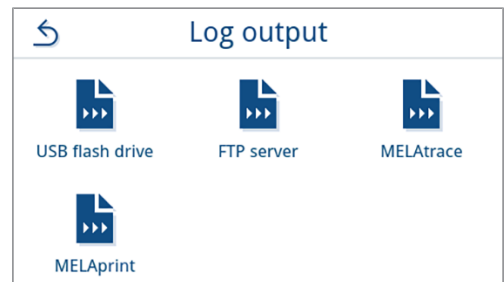
→ The selection has been set as default and the view changes back to the **Log output** submenu.

Log output on a FTP server

1. Press **Log output** in the **Settings** menu.

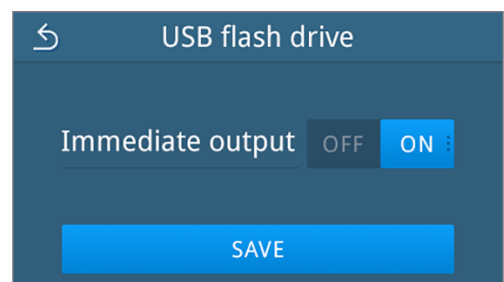


2. Press **FTP server**.



3. Press **ON** or **OFF** to activate or deactivate the immediate output.

4. Press **SAVE**.

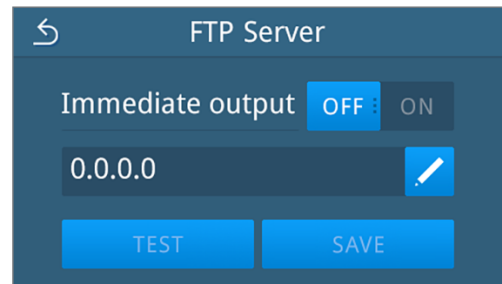



→ The selection has been set as default. The view switches back to the **Log output** submenu.

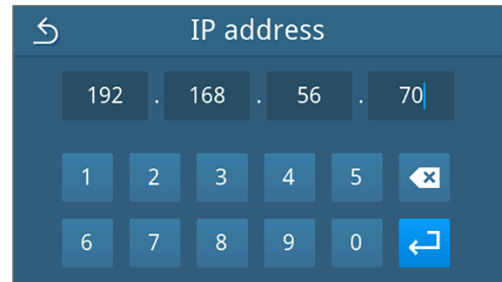
5. Set up the FTP server.


Configure a FTP server

1. Configure the FTP server by pressing  in the bottom row.




2. Enter the IP address and accept the changes by confirming with .




 The view for changing the user name is displayed.

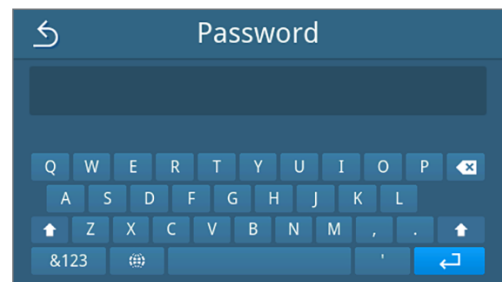
3. Enter the user name of the FTP server and accept the changes by confirming with .


PLEASE NOTE: If an alternative keyboard is used in your region, you can select your preferred keyboard by pressing .



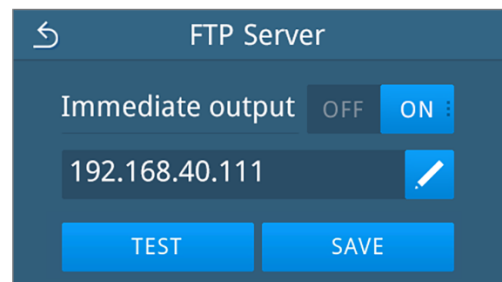
 The password entry view is displayed.

4. Enter the password of the FTP server and accept the changes by confirming with .



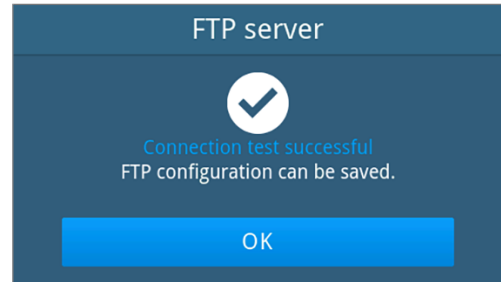
 The view for selecting the output type is displayed again.

5. After a setting has been changed, the **TEST** and **SAVE** buttons are active. Press **TEST** to check the connection with the FTP server settings.

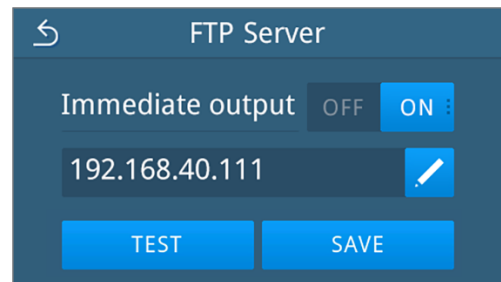


6. Confirm with **OK**.

If the connection test fails, check your entries and test again.



7. Press **SAVE**.



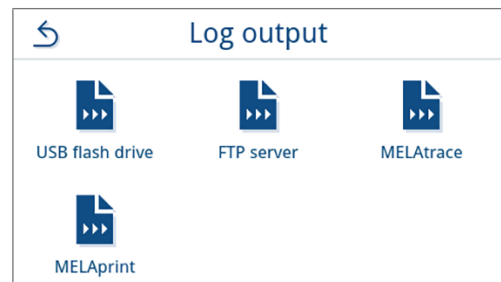
→ The selection has been set as default and the view changes back to the **Log output** submenu.

Log output with MELAtrace

1. Press **Log output** in the **Settings** menu.

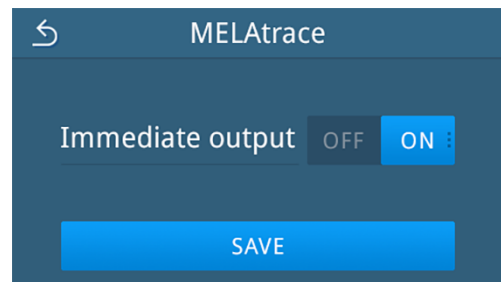


2. Press **MELAtrace**.



3. Press **ON** or **OFF** to activate or deactivate the immediate output.

4. Press **SAVE**.

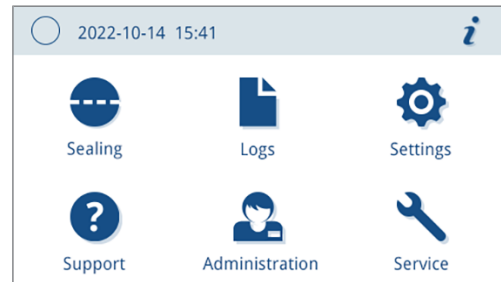


→ The selection has been set as default. The view switches back to the **Log output** submenu.

Administrative settings

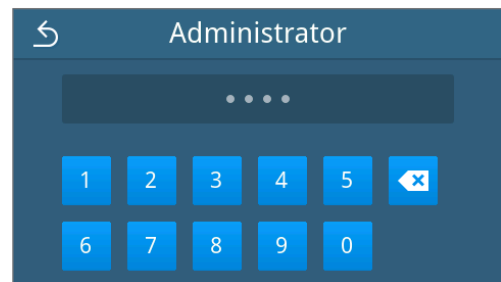
To make administrative settings, such as changes in user administration, you must log in as an administrator.

1. In the main menu, press **Administration**.



2. Enter the associated PIN.

PLEASE NOTE: The PIN must be re-entered each time the menu is opened.

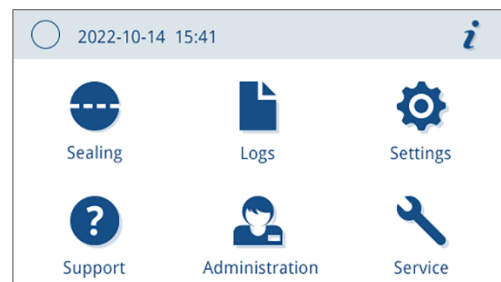


➔ The **Administration** menu is displayed.

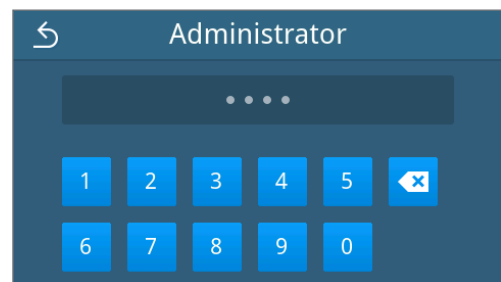
Logging in and out of the user role

1. In the main menu, press **Administration**.

PLEASE NOTE: The **Service** area is reserved for service technicians.



2. Enter the associated PIN.



➔ Further setting options are now available in the menu.

➔ If the login was successful, the **Administration** menu is displayed.

Logging out as an administrator

- ▶ Exit the **Administration** menu to log out as administrator.

➔ After logging out, the main menu is displayed.

Admin PIN

When the device is delivered, the admin PIN is set to 1000 by default. MELAG recommends that you change the admin PIN upon commissioning.



PLEASE NOTE

If the changed Admin PIN is lost, contact an authorised technician.

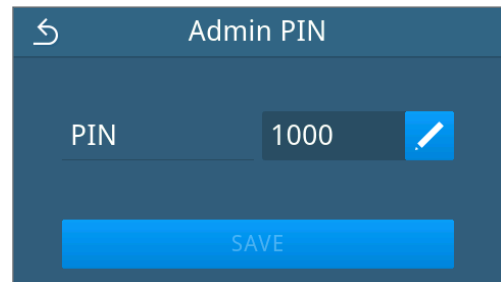
The following must be fulfilled or present:

- ✓ You are logged in as an administrator or service technician, see [Logging in and out of the user role](#) [▶ Page 42].

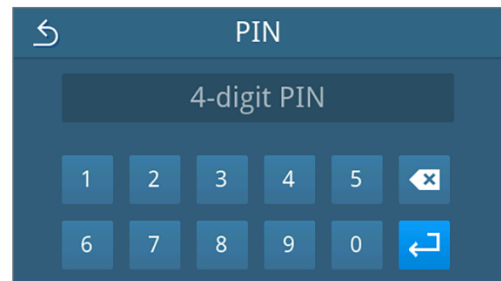
1. Press **Admin PIN** in the **Administration** menu.



2. Press .

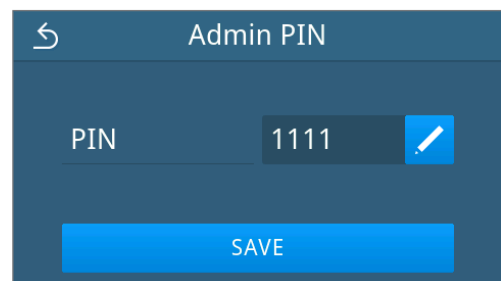


3. Enter the new four-digit PIN and confirm with .



➔ After a setting has been changed, the **SAVE** button is active.

4. Press **SAVE**.



➔ The view switches back to the **Administration** menu.

Authentication

Authentication is deactivated by default.

The following must be fulfilled or present:

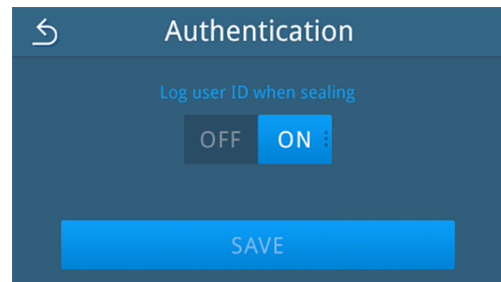
- ✓ You are logged in as an administrator or service technician, see [Logging in and out of the user role](#) [▶ Page 42].
- ✓ Users have been created, see [Users](#) [▶ Page 45].

1. Press **Authentication** in the **Administration** menu.

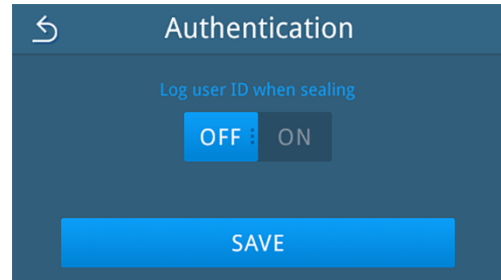


2. Press the respective **OFF/ON** button to deactivate/activate authentication.

Example of the program type "reprocessing program"



3. After a setting has been changed, the **SAVE** button is active. Press **SAVE** to accept the setting.



↩ The view switches back to the **Administration** menu.

Users

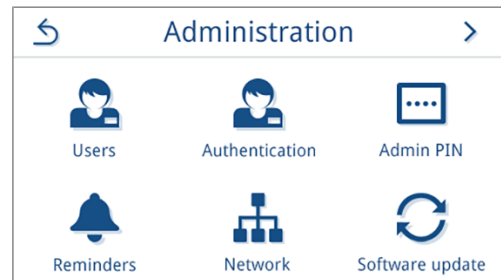
An individual ID and user PIN can be issued to every user to facilitate reliable traceability. The user can authenticate himself with the user PIN, see [Authentication](#) [▶ Page 44].

Adding a user

The following must be fulfilled or present:

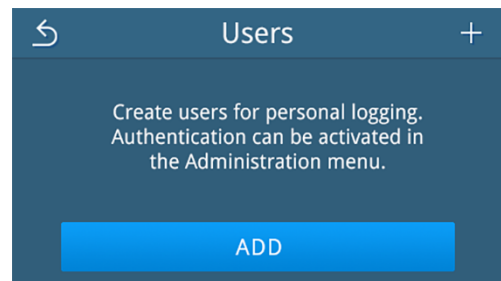
- ✓ You are logged in as an administrator or service technician, see [Logging in and out of the user role](#) [▶ Page 42].

1. Press **Users** in the **Administration** menu.



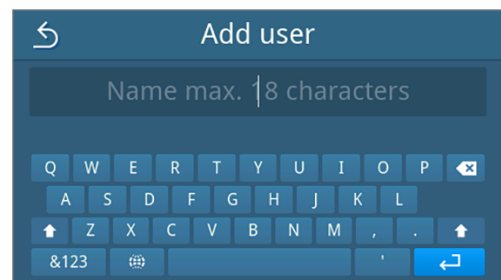
2. If there is no user in the system, a message is displayed and the option to create a user.

Press **ADD** or .



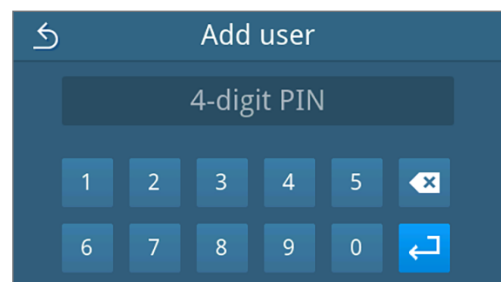
3. Enter the user name and confirm your entry with .

PLEASE NOTE: If an alternative keyboard is used in your region, you can select your preferred keyboard by pressing .




→ The view for assigning a PIN is opened.

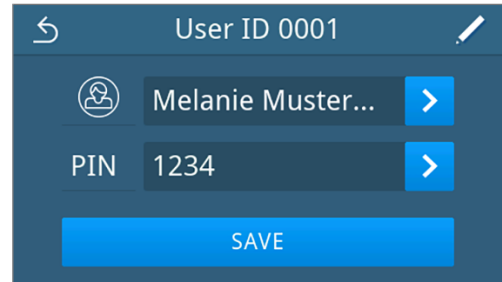
4. Enter a four-digit PIN and confirm your entry with .




→ The user entry view is displayed.

- 5. A user ID is assigned and displayed in the title. All components of the user entry can be via edited again by pressing .

Press **SAVE** to accept the user entry.





 The user list view is displayed.



Editing a user

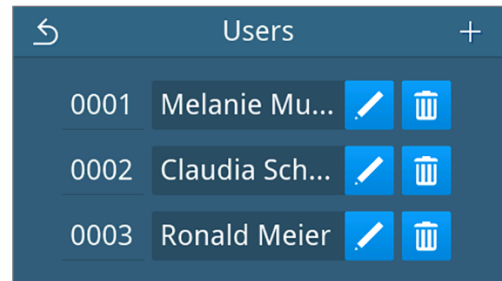
The following must be fulfilled or present:

- ✓ You are logged in as an administrator or service technician, see [Logging in and out of the user role](#) [▶ Page 42].

1. Press **Users** in the **Administration** menu.
2. If created users exist, a list of user entries is displayed. The entries are sorted in ascending order by user ID.

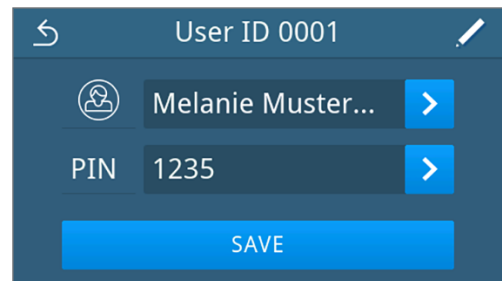
Press  to edit the selected user entry or  to delete the entry.


Press  or  to scroll through the list.



 The view for editing the user entry is displayed.

3. Change the user entry.
4. Press **SAVE** to accept the entries.



 The user list view is displayed.

Reminders

The reminders are deactivated by default.

The following must be fulfilled or present:

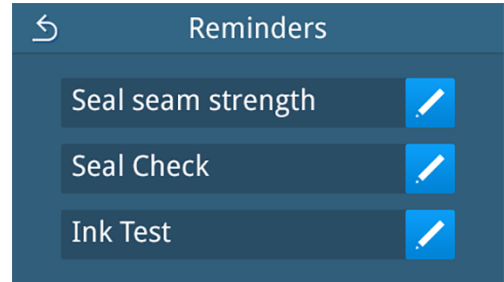
- ✓ You are logged in as an administrator or service technician, see [Logging in and out of the user role](#) [▶ Page 42].

1. Press **Reminders** in the **Administration** menu.



 The adjustable reminders are displayed.

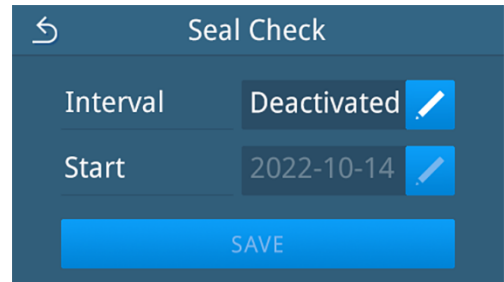
- Press  of the respective reminder to edit it.



→ The view of the current reminder settings is displayed.

- Press  next to **Interval**.

Example view of the menu Seal Check.





→ The view for setting the interval is displayed.

- The device-specific recommendation for the selected reminder is displayed as a note above the selection.

Select the interval using  or .

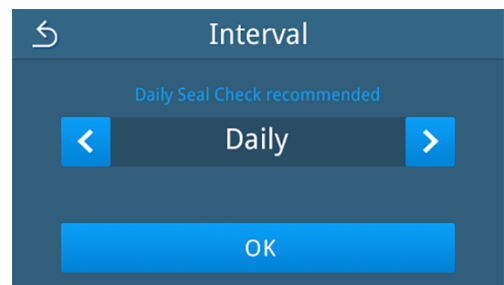
TIP:


-  Interval ascending
-  Interval descending

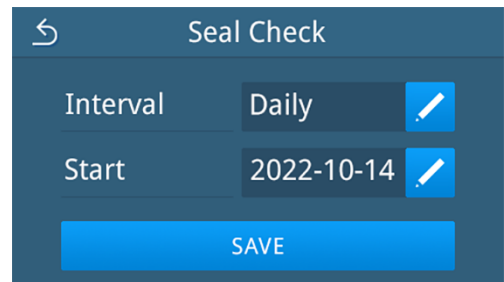
→ The view rotates between the intervals (Daily/Weekly/Bi-weekly/Monthly/Bi-monthly/Annually).

- Press **OK** to confirm the setting.



→ The view of the current settings with editable interval start is displayed.



- Press  next to **Start** to edit the date of the interval start.




→ The calendar view is displayed.

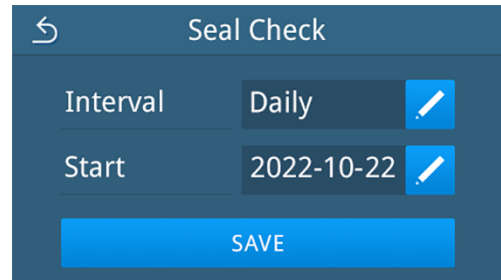
- Select the desired date in the calendar.
Press  (past) or  (future) to select the month.


TIP:
press and hold = 1-year increments



 The current settings view is displayed.

- Press **SAVE**.



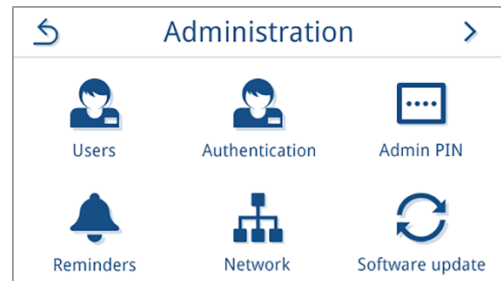
 The view switches back to the **Administration** menu.

Network

You can select an automatic configuration via DHCP or enter the required address details manually. DHCP is activated by default.

Manual (static) entry

- Press **Network** in the **Administration** menu.

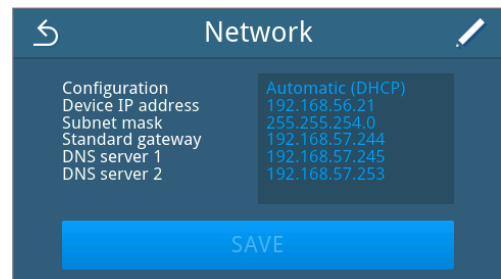


 The current network configuration view is displayed.



- The entries are inserted automatically if the device is integrated in the practice network with a DHCP server. If there is no DHCP server, the entries remain empty.

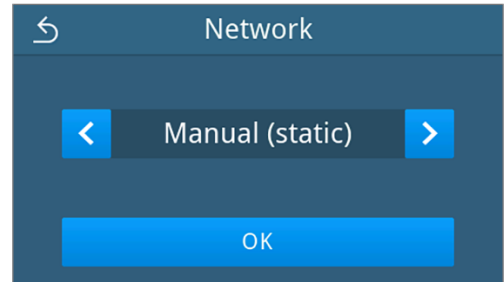
Press  to edit the network settings.


Example view of a network setting.



 The view for editing the network settings opens.


- Use  or  to select the setting **Manual (static)** and confirm the selection with **OK**.



 The view for editing the IP address is displayed.


- Enter the IP address of your network and confirm the selection with .



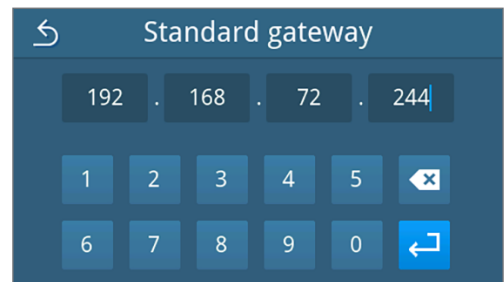
 The view for editing the subnet mask is displayed.

- Enter the address of the subnet mask of your network and confirm the selection with .



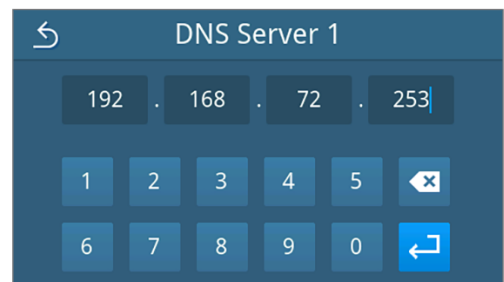
 The view for editing the default gateway is displayed.

- Enter the address of the default gateway of your network and confirm the selection with .



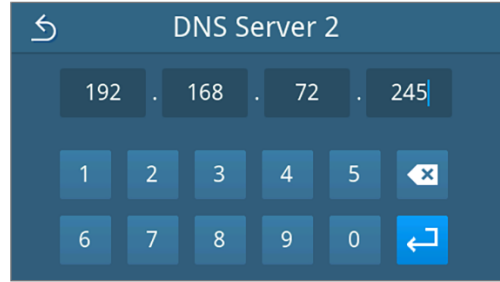
 The view for editing DNS server 1 is displayed.

- Enter the address of the DNS server 1 of your network and confirm the selection with .



 The view for editing DNS server 2 is displayed.

- Enter the address of the DNS server 2 of your network and confirm the selection with .



→ The view of edited network settings is displayed.

- Press **SAVE**.



→ The view switches back to the **Settings** menu.

Software update

A software update can only be performed by the administrator or ►authorised technician.



PLEASE NOTE

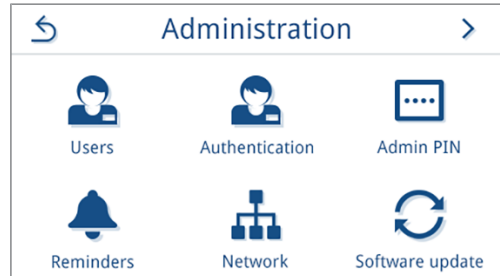
During a software update, all sealing and malfunction logs are deleted.

- Check whether all required logs have been output to an output medium.
- Please observe the further information in the separate instruction "Information regarding software update and re-installation". You can find the document in the download centre on our website at www.melag.com/en/service/downloadcenter.

The following must be fulfilled or present:

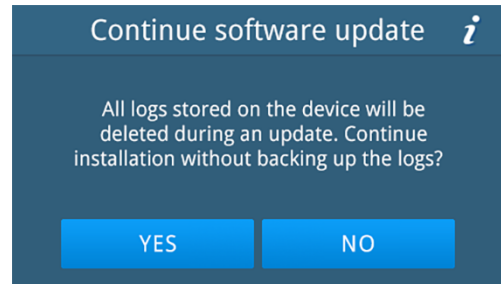
- ✓ USB flash drive with the current update files.
- ✓ All logs of the internal log memory are output, see [Subsequent log output](#) [► Page 23].
- ✓ You are logged in as an administrator or service technician, see [Logging in and out of the user role](#) [► Page 42].

- Press **Software update** in the **Administration** menu.

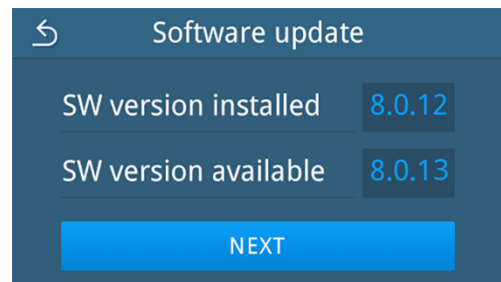


- Insert a USB flash drive with the installation data into the USB connection on the display.

3. Confirm the notification for log backup with **YES**.



4. Press **NEXT** to perform the software update.



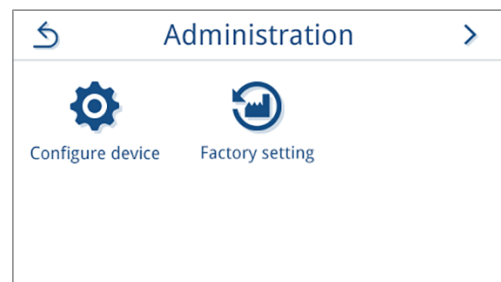
➔ During the software update, the device independently performs one or more restarts.

Configuring the device

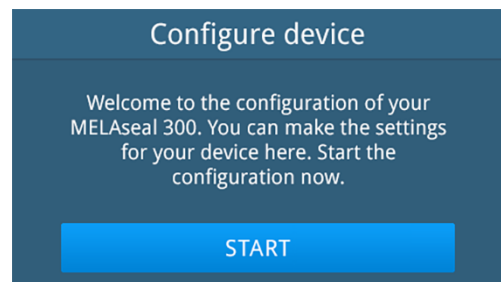
Settings on the device can also be adjusted using the configuration wizard.

- ✓ You are logged in as administrator and are in the **Administration** menu.

- ▶ Press **Configure device**.



1. Press **START** to start the configuration wizard.

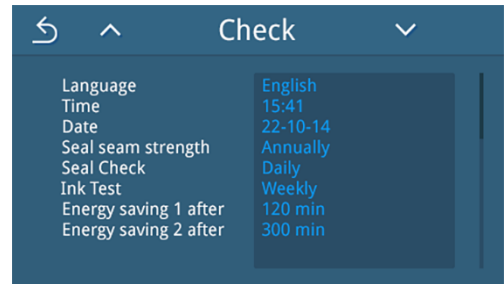


2. Follow the configuration wizard and configure the device according to your requirements.

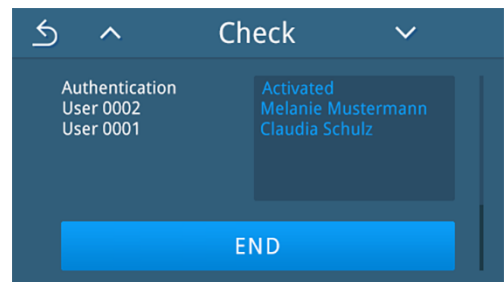
➔ For more detailed information on the individual setting options, see [General settings](#) [▶ Page 28].

3. Check your settings in the displayed overview.

Example view of device settings



4. Press **END** to end the configuration wizard and restart the device.



Factory setting

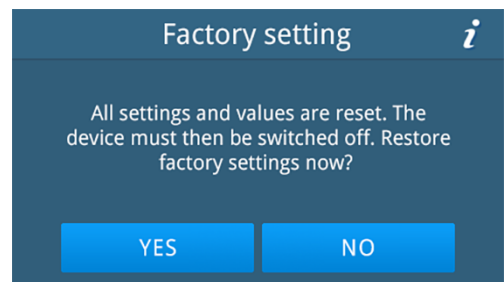
You have the option of resetting the device to the factory settings. All settings and saved values will be lost.

- ✓ You are logged in as administrator and are in the **Administration** menu.

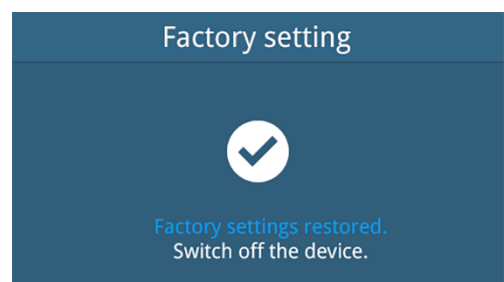
1. Press **Factory setting**.



2. Confirm the security query with **YES** to restore the factory settings.



3. Switch off the device at the power switch.



9 Maintenance

Cleaning and regular checks

Comply with the following for safe handling:

- Switch off the sealing device at the mains and remove the cable before cleaning.
- The cleaning cloth may never be allowed to become entirely wet in order to prevent water from entering the interior of the sealing device.
- Liquids may not be permitted to reach the interior of the device. This could result in an electrical shock or short circuiting.
- The fan must not be clogged or blocked. Failure to comply with this provision can result in the overheating of the electrical components in the interior of the device and malfunctions.
- Check the ventilation slots regularly for cleanliness in order to prevent it from becoming clogged with dust and thereby preventing insufficient cooling.

Interval	Measure
When necessary and every 6 months	Clean the exterior of the sealing device with a dry or damp, non-fuzzing cloth and where necessary with a neutral fluid cleaner or spirit. Only at persistent soiling, use a mild stainless steel cleaning agent with a pH value between 5 and 8.
Annually	Clean the fan on the base of the sealing device with a dry or damp, non-fuzzing cloth in order to prevent it from becoming clogged with dust and insufficient cooling.

Maintenance

Comply with the following for safe handling:

- Maintain the specified maintenance intervals. Continuing operation beyond the maintenance interval can result in malfunctions in the device.
- Have maintenance performed only by trained and authorised technicians using the original MELAG maintenance set.
- If components that are not included in the maintenance set have to be replaced during maintenance, only original spare parts from MELAG may be used for the replacement.

Regular maintenance is vital to ensure reliable operation and value retention of the device. All function and safety-relevant components and electrical units are checked during maintenance and replaced where necessary.

Maintenance is to be performed after every 100,000 sealing procedures (cycles), but after 4 years at the latest. At the appropriate time, a warning message is shown on the display.

Validation

Your sealing device complies with all standard requirements for the validation of the sealing procedure in accordance with [EN ISO 11607-2](#). Conformity is confirmed with the declaration of conformity included in the scope of delivery.

10 Pause times

Pause times

The sealing device can remain switched on over longer operating pauses of many hours. The sealing device automatically switches to energy-saving mode after a user-defined time, see [Energy saving](#) [▶ Page 31]. MELAG recommends switching off the device during long operating pauses to save energy and for safety reasons.

Transport and storage



NOTICE

• **Damage to the housing and the device interior as a result of using unsuitable transport packaging.**

- Only transport the device in its original packaging or other suitable packaging.
-

Note the following:



- Store and transport the device frost-free.
- Avoid strong shocks/vibrations.
- Store the device in a fashion protected against moisture.

11 Malfunctions

Comply with the following for safe handling:

- Should the device issue the same malfunction message repeatedly, turn off the device and if necessary, inform your stockist.
- The device may only be serviced by ► [authorised technicians](#).

Not all notifications on the display are malfunction messages. Warning and malfunction messages are issued on the display with an event number. This number serves identification purposes.

Type of message		Description
	Warning message	A warning message helps to ensure malfunction-free operation and recognition of undesirable events. React to warning messages quickly to prevent the resulting malfunction.
	Malfunction messages	A malfunction message is issued when it is not possible to ensure safe operation or safety of sterilization. These can appear on the display shortly after switching on the device or during a program run. If a malfunction occurs during sealing, this sealing procedure is considered unsuccessful.

Troubleshooting online



All messages with current descriptions can be found in the Troubleshooting portal on the MELAG website (<https://www.melag.com/en/service/troubleshooting>).

Reading and acknowledging messages

Any messages that occur are immediately displayed on the device.

1. Read the message.
2. Acknowledge the message with **OK**.

➔ Acknowledged messages cannot be displayed again. Malfunction messages can be viewed subsequently in the logs.

Before contacting customer services

Follow the instructions that appear on the display in connection with a message.

The following tables indicate possible causes for certain messages/events and the corresponding operating information for their remedy. Should you be unable to find the relevant event, or your efforts do not redress the problem, you can contact your nearest stockist or authorised MELAG customer service provider. Have the following information ready:


- The serial number of your device (see type plate or device status info)
- The event number and/or
- A detailed description of the message

Warnings and malfunction messages



PLEASE NOTE

Further information and measures relating to the messages can also be found in the troubleshooting portal on the MELAG website.

- Press  in the warning or malfunction message. Follow the QR code displayed to access the MELAG website.
- If malfunctions occur repeatedly, check the software version of the device malfunction and carry out a software update if necessary.
- If the malfunction continues to occur, contact technical service.

Event	Possible causes	What you can do
36512	There is no paper in the printer.	Replace the empty paper roll with a new one.
36731	No USB flash drive is connected.	<p>For logging:</p> <ol style="list-style-type: none"> 1. Connect a functional USB flash drive. 2. Connect the USB flash drive to the second USB interface. 3. Use a different USB flash drive. 4. If both USB interfaces are defective, contact technical service. <p>Without logging:</p> <p>Deactivate the log output in the Settings > Log output > USB flash drive menu.</p>
40001	The sealing temperature is too low.	Restart the device.
40002	The sealing temperature is too high.	Restart the device.
40003	The conveying speed is too low.	Restart the device.
40004	The conveying speed is too high.	Restart the device.
40005	The sealing force is too low.	Restart the device.
40006	The sealing force is too high.	Restart the device.
40007	An electrical error has occurred at the temperature sensor (open load, short circuit).	Restart the device.
40008	The temperature of the electronics is too high (PCB).	Restart the device.
40009	An electrical error has occurred at the force sensor (open load, short circuit).	Restart the device.
40010	An electrical error has occurred at the heater (open load).	Restart the device.
40011	An RTC error occurred.	Restart the device.
10012	A software update is not possible.	<ol style="list-style-type: none"> 1. Check whether the update file on the USB flash drive is suitable for your device. 2. Check whether the USB flash drive is functional and is detected by the device. 3. Use the second USB interface on the device for the update. 4. If this occurs repeatedly, contact the technical service.
40015	Heater timeout - The heating time is too long.	Restart the device.
40016	The motor is overloaded.	Restart the device.
40017	An electrical fault has occurred at the light barrier (open load, short circuit).	Restart the device.
40018	The BASM was not recognised.	Restart the device.
40019	No serial number is entered in the device.	Restart the device.
40020	A malfunction has occurred at the motor.	Restart the device.
40025	A connection error to MELAtrace has occurred.	Check the configuration in the settings, see Log output with MELAtrace.
40026	There is insufficient memory on the USB flash drive.	Backup the log data located on the USB flash drive onto the practice network. Remove all data from the USB flash drive. Alternatively, use a different USB flash drive with sufficient memory.
40033	The Seal Check was not successful.	<ol style="list-style-type: none"> 1. Carry out a sealing procedure without a Seal Check and check the seal seam. 2. If the seal was successful, carry out a seal with a Seal Check. 3. If the sealing procedure was not successful without a Seal Check or if it occurs repeatedly, contact the technical service.
40047	A malfunction has occurred at the fan.	Restart the device.

Malfunction logs

In the **Logs > Malfunctions** menu, you can view malfunction logs and output them to a USB flash drive, see [Subsequent log output](#) [▶ Page 23].

12 Manufacturer's recommendation for routine operation

For further information see separate document "Manufacturer's recommendation for routine operation of MELAG sealing devices".

Performing the peel test

1. Seal a transparent sterilization package in the sealing device.
2. Perform a visual check to verify whether the seal seam extends consistently along the whole width and length of the sterilization package just sterilized. No paper residue bigger than 10 mm is permitted on the seal seam.
3. Process the sealed transparent sterilization package in a sterilization cycle.
4. Working by hand, pull the seal seam apart slowly along the direction of peeling:
 - ↳ The seal seam produced by your sealing device must offer noticeable resistance when opened.
 - ↳ The paper must not tear when opened.
5. Document the results.

MELAG seal seam stability test

Video tutorial

See also "Test for seal seam stability" (<https://www.melag.com/en/service/tutorial/sealing-unit>).



To ensure that the sealing procedure complies with all normative specifications, MELAG recommends carrying out an annual seal seam stability test.

MELAG offers a seal seam stability test for the validation of your sealing procedures. After testing the film test strips, you will receive a certificate from MELAG stating the conformity of the seal seams with the ▶EN 868-5 standard, Appendix D, if the seal seam stability test is successful. Use the MELAG seal seam stability test application form. Download the application form from the MELAG website (Service/Download Center).

13 Standard specifications

Explanation of terms

Name	Description
Sterile barrier system	►EN ISO 11607-2 replaces the terms “packaging”, “end packaging” and “primary packaging” with the single term “sterile barrier system”. A sterile barrier system is the minimum level of packaging which prevents the penetration of micro-organisms and permits aseptic provision of the product at the location of use. This includes transparent sterilization packages, a sterilization bag, reusable containers etc.
Protective packaging	The protective packaging is designed to provide the sterile barrier system with protection up until its final application.
Packaging system	The sterile barrier system and protective packaging combine to form the packaging system.
Peel test	A procedure to determine the peeling characteristics of paper-/plastic composite material in accordance with ►EN 868-5, Appendix E.

General information regarding the packaging and sealing procedure

Comply with the following during wrapping and sealing:

- Choose packaging of a sufficient size.
- Packaging made of porous materials and plastic composite film should be filled to a max. of 3/4 of its volume (►DIN 58953-7).
- For packaging made of porous materials and plastic composite film, at least 30 mm must remain free between the sterilization material and the seam to be sealed (DIN 58953-7).
- When using transparent sterilization packages from a reel, the removal side must have an overlap of min. 10 mm between the cutting edge and the seal seam, enabling an aseptic removal (DIN 58953-7).
- Press together to remove all air before sealing.

Seal seam width

- The recommended nominal size for the width of the seal seam in DIN 58953-7 is 6 mm. Section 4.3.2 of EN 868-5 requires total seal width of at least 6 mm. Thus for grooved seal seams, the sum of the individual grooved seams should amount to at least 6 mm.

Clearance of the seal seam to the cutting edge

- Maintain the clearance between seal seam and cutting edge as prescribed in the standard: DIN 58953-7 requires the maintenance of a sufficient overhang between the seal seam and the cutting edge when working with film pouches on the removal side. This ensures aseptic removal. MELAG recommends a minimum overhang of 10 mm.

Seal seam stability

When using MELAfol transparent sterilization packages, the sealing device guarantees a seal seam stability in accordance with EN 868-5.

Storage duration for sterile medical devices

The maximum storage time is dependent on the packaging and the storage conditions. Please observe the regulatory requirements for the storage period of ►sterile materials (in Germany e.g. ►DIN 58953, Part 8 or the ►DGVS guidelines) as well as the following listed criteria:

- Store the sterile material in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterile material in an environment protected against moisture.
- Store the sterile material in an environment protected against excess temperature variations.

14 Technical Data

Device type	MELAseal 300
Device dimensions (W x D x H)	36 x 16 x 17.5 cm
Weight	5.6 kg
Electrical connection	
Power supply	220-230 V, 50/60 Hz
Electrical power	max. 650 W
Device fuse	1x 8 A
Overheat protection	> 220 °C
Length of the power cable	1.5 m
Ambient conditions	
Installation location	interior of a building
Max. altitude	3000 m
Ambient temperature	5-40 °C (ideal range 16-26 °C)
Relative humidity	max. 80 % at 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)
Sealing characteristics	
Sealing speed	5-15 m/min
Sealing temperature range	100-215 °C
Heating duration (from 25 °C to 180 °C)	100 s
Sealing force	50 N ± 10 %
Seal seam width	12 mm
Seal seam length	unlimited

15 Accessories and spare parts

All specified articles are available through specialist dealers.

	Article	Art. no.
Accessories	Work table Comfort	ME00141
	Work table Standard	ME77750
	Wall mounted reel dispenser with cutting device	ME00116
	Flex roll holder (available from the end of 2024)	ME00142
	MELAcontrol Seal Check	ME01079
	MELAcontrol Ink Test	ME01089
Films	MELAfol 501 (pouch, 5 x 25 cm, 1000 pcs.)	ME00501
	MELAfol 502 (roll, 5 cm x 200 m)	ME00502
	MELAfol 751 (pouch, 7.5 x 25 cm, 1000 pcs.)	ME00751
	MELAfol 752 (roll, 7.5 cm x 200 m)	ME00752
	MELAfol 1001 (pouch, 10 x 25 cm, 1000 pcs.)	ME01001
	MELAfol 1002 (roll, 10 cm x 200 m)	ME01002
	MELAfol 1502 (roll, 15 cm x 200 m)	ME01502
	MELAfol 2002 (roll, 20 cm x 200 m)	ME02002
	MELAfol 2051 (side gusset bag, 20 x 50 cm, 100 pcs.)	ME02051
	MELAfol 2502 (roll, 25 cm x 200 m)	ME02502
For the documentation	MELAprint 80 universal printer	ME01108
	USB flash drive	ME19901
Spare parts	Power cable C13 type E+F	ME59160
	Fuse 8A-F	ME80093

Glossary

Authorised technician

An authorised technician is a person intensively trained and authorised by MELAG who has sufficient specific device and technical knowledge. to perform maintenance and installation work on MELAG devices. Only they may carry out this work.

Batch

The batch is the summary of seals that, for example, run through the same reprocessing procedure together or belong to the same instrument set.

DGSV

DGSV is the abbreviation for "Deutsche Gesellschaft für Sterilgutversorgung" [German Society for Sterile Supply]. The training guidelines of the DGSV are listed in DIN 58946, Part 6 as requirements for personnel.

DIN 58953

Standard for "Sterilization – Sterile supply"

DIN 58953-7

Standard for "Sterilization – Sterile supply – Part 7: Application technology for sterilization paper, nonwovens, paper bags and sealable transparent bags and tubes"

EN 868-5

Standard for "Packaging for medical devices to be sterilized in the final packaging – Part 5: Sealable transparent bags and tubes made of porous materials and plastic composite film - Requirements and test methods"

EN ISO 11607-2

Standard for "Packaging for medical devices to be sterilized in the final packaging – Part 2: Validation requirements for forming, sealing and assembly processes"

Qualified electrician

The qualified electrician has the suitable technical training, knowledge, and experience to recognise and avoid hazards that can be caused by electricity, see IEC 60050 or for Germany VDE 0105-100.

Sterile material

Sterile goods are successfully sterilized (i.e. sterile) goods. Sterile goods are also referred to as batches.



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Original instructions

Responsible for content: MELAG Medizintechnik GmbH & Co. KG
We reserve the right to technical alterations

Your stockist